# Exhibit A

UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

| | |
|---|---|
| IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION | Master File No. 2:12-MD-02327 MDL No. 2327 |
| _____ | JOSEPH R. GOODWIN |
| THIS DOCUMENT RELATES TO: All TVT-O Cases | U.S. DISTRICT JUDGE |

VIDEOTAPED DEPOSITION OF EXPERT WITNESS

MAREENI STANISLAUS, M.D.

Paso Robles, California

Friday, July 15, 2016

Reported by: Ashala Tylor, CSR No. 2436, CLR, CRR, RPR

Job #136049

I N D E X

WITNESS: MAREENI STANISLAUS, M.D.



EXHIBITS

E X H I B I T S (continued)

E X H I B I T S (continued)



INFORMATION REQUESTED

(None)

QUESTIONS NOT ANSWERED

Page 47, Line 6

UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

| | |
|---|---|
| IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION | Master File No. 2:12-MD-02327 MDL No. 2327 |
| _____ | JOSEPH R. GOODWIN |
| THIS DOCUMENT RELATES TO: All TVT-O Cases | U.S. DISTRICT JUDGE |

The videotaped deposition of MAREENI STANISLAUS, M.D., the expert witness, was taken at Courtyard Paso Robles, 120 South Vine Street, Paso Robles, California, on Friday, July 15, 2016, at 1:04 p.m., before Ashala Tylor, CSR No. 2436, Certified Shorthand Reporter in and for the State of California, RPR, CRR, CLR.

A P P E A R N C E S

FOR THE PLAINTIFFS:

WEXLER WALLACE LLP
BY: TIM E. JACKSON, ESQ.
55 West Monroe Street, Suite 3300
Chicago, Illinois 60603
312.346.2222
tej@wexlerwallace.com

FOR DEFENDANTS:

BOWMAN AND BROOKE LLP
BY: BARRY J. KOOPMANN, ESQ.
150 South Fifth Street, Suite 3000
Minneapolis, Minnesota 55402
612.339.8682
barry.koopmann@bowmanandbrooke.com

Also Present: Michael Brewer, Videographer

Friday, July 15, 2016; 1:04 p.m.

Paso Robles, California

THE VIDEOGRAPHER: Good afternoon. We are on the record. My name is Michael Brewer. I'm a videographer for Golkow Technologies.

Today's date is July 15th, 2016, and the time is 1:04 p.m.

This video deposition is being held in Paso Robles, California in the matter of Ethicon, Incorporated Pelvic Repair System Products Liability Litigation for the United States District Court, Southern District of West Virginia at Charleston. The deponent is Dr. Mareeni Stanislaus.

At this time will counsel please identify themselves and state whom they represent.

MR. JACKSON: Tim Jackson from Wexler Wallace on behalf of the Plaintiffs.

MR. KOOPMANN: Barry Koopmann from Bowman and Brooke on behalf of Ethicon and Johnson & Johnson.

THE VIDEOGRAPHER: Thank you. The court reporter is Ashala Tylor and will now swear in the witness.

///

///

MAREENI STANISLAUS, M.D.,

having been first placed under oath,

was examined and testified as follows:

THE VIDEOGRAPHER: You may begin.

EXAMINATION

BY MR. JACKSON:

Q. Doctor, could you please state and spell your name for the record?

A. Mareeni Stanislaus. I'm sorry. Mareeni Therese Stanislaus, M.D.

Q. Could you please spell that for the record?

A. Yes. M-A-R-E-E-N-I, middle name T-H-E-R-E-S-E, last name Stanislaus, S-T-A-N-I-S-L-A-U-S.

Q. Okay. Thank you.

Doctor, I introduced myself to you before we got on the record, but my name is Tim Jackson, and I'm from a law firm called Wexler Wallace in Chicago. And you're here today to give testimony about your TVT-O report in this case; is that correct?

A. That is correct.

Q. Okay. And is there any reason you feel you cannot testify fully and accurately today?

A. No.

Q. If I ask something and it's not clear what I'm asking, I'd just ask that you let me know that and I'll do my best to rephrase the question so you understand it. Is that fair?

A. Certainly.

Q. Okay. And, conversely, if I ask a question and you answer it, is it fair to assume that you understood the question?

A. Yes.

Q. Okay. Have you ever had your deposition taken before?

A. Yes.

Q. Okay. And how many times?

A. Approximately five.

Q. When was the most recent?

A. In relation to this case, two weeks ago.

Q. Okay. And was that for a plaintiff specific report?

A. Yes.

Q. Okay. And were there any other times in relation to this case or just that one?

A. Just that one.

Q. Okay.

A. There were three consecutive depositions that day.

Q. Okay. So are you counting those three separate depositions in your total of five?
A. Yes.
Q. Okay. So there were two other instances where you had your deposition taken?
A. Yes.
Q. Okay. And what -- can you tell us what those two other instances were?
A. They were in regards to malpractice litigation.
Q. Okay. And were you a defendant in those cases?
A. Yes.
Q. Okay. In both of them?
A. Yes.
Q. Okay. And can you tell us what the dates of those two cases were?
A. They were subsequently dropped without prejudice. 2002, I think, and perhaps 2007.
Q. Okay. Thank you.
And, Doctor, prior to this case, have you ever been retained as an expert witness before?
A. No.
Q. Okay. Doctor, what did you do to prepare for your deposition today?

A. I reviewed textbooks. I reviewed my reliance materials. I reviewed some of the literature and reviewed my report.

Q. Okay. And when you say you reviewed textbooks, would those be books that are listed on your reliance materials?

A. I believe so, yes.

Q. Okay.

A. And, I'm sorry, I also consulted with my counsel.

Q. Okay. I'm sorry, Doctor. When you say your counsel, do you mean counsel for Ethicon?

A. Counsel for Ethicon, yes.

Q. And, Doctor, can you give me your best guess of about how many hours you spent just preparing for the deposition today aside from writing the report?

A. Oh, four hours.

Q. And aside from counsel, did you speak to anyone else in regards to the deposition today prior to the deposition?

A. No.

Q. Doctor, before we got on the record -- strike that.

Before we got on the record we premarked as Exhibit 1 this. And can you please confirm that that is

a true and accurate copy of the report you provided in this case.

(Exhibit 1 was marked for identification and attached hereto.)

(Pause while witness peruses document.)

THE WITNESS: Yes.

BY MR. JACKSON:

Q. Doctor, we've premarked as Exhibit 2 what I'll represent is the CV that was provided along with your report.

(Exhibit 2 was marked for identification and attached hereto.)

BY MR. JACKSON:

Q. Does that look like a reasonably accurate copy of your CV?

A. Yes.

Q. Okay. And, Doctor, what's been marked as Exhibit 3 is the Mareeni Stanislaus reliance list in addition to materials referenced in reports that were provided with your report in this case.

(Exhibit 3 was marked for identification and attached hereto.)

BY MR. JACKSON:

Q. Does that look reasonably correct to you? It's a very long document. I'm not asking you to look

at every page.

A. I'm reading it --

(Pause while witness peruses document.)

Q. Okay. Doctor, Exhibit 4 is the Notice of Deposition for this case. Have you seen that document before?

A. Yes, I have.

(Exhibit 4 was marked for identification and attached hereto.)

BY MR. JACKSON:

Q. Okay. Doctor, that document asks you to bring certain documents with you today. You have those documents; is that correct?

A. Yes. I'm not sure that the correct documents were requested because these documents seem to refer to patient information, which I don't have, but I did bring all documents that I have related to my general report.

Q. Okay. And, just generally, can you tell us what you brought with you today?

A. My report, my reliance list, literature, various articles.

Q. Okay. And, Doctor, I believe you have a binder in front of you. Can you tell us what that specific binder is?

A. That is my general report with the articles

cited in my report.

MR. JACKSON: Okay. And could we go ahead and mark that binder as Exhibit 5.

(Exhibit 5 was marked for identification and attached hereto.)

BY MR. JACKSON:

Q. Doctor, is it fair to say that -- I'm sorry. Doctor, is it fair to say that all of the footnotes from your report are contained in that binder?

A. Yes.

Q. Have you written or highlighted on any of the documents in the binder or are they clean copies?

A. They're clean copies.

Q. Okay. And, Doctor, aside from the binder we've marked as Exhibit 5, you also brought a number of other binders with you today, correct?

A. Yes, I did.

Q. And do those represent the reliance materials you have in this case?

A. Yes, they do.

Q. Okay. And would it be fair to say that the other binders, aside from Exhibit 5, are the same as the documents listed on Exhibit 3, the reliance list?

A. Yes. I'm not entirely sure if they're all in there, but I think so.

Q. Okay. Is it fair to say there wouldn't be any new documents in the binders that are not on the reliance list?

A. Yes, that would be fair to say.

Q. And I think what I'd like to do, if we could, is mark all the other binders, aside from Exhibit 5, as Exhibit 6 collectively. And then when we're on a break, I can look at those a little more carefully.

Doctor, did you also bring some thumb drives with you today?

A. Yes, I did.

Q. Okay. And what's on those thumb drives?

A. The complete set of documents and articles related to this case that I reviewed. They principally are the same as what is in these binders.

MR. JACKSON: Could we mark the thumb drives as Exhibit 7?

(Exhibit 7-A was marked for identification and attached hereto.)

(Exhibit 7-B was marked for identification and attached hereto.)

BY MR. JACKSON:

Q. Doctor, when were you first contacted about providing a report in this case?

A. I don't remember the exact date, but I would

say sometime in the last eight, nine months.

Q. Sometimes in the last eight, nine months. Could you be any more specific than that? I mean, was it, you know, was it the spring of 2016?

A. It was probably the fall of 2015, yes.

MR. KOOPMANN: Just make sure that he gets to finish his question before you start answering so the court reporter can take everything down.

BY MR. JACKSON:

Q. So, Doctor, you were first contacted in the fall of 2015, approximately, about providing a report in this case; is that correct?

A. That is correct.

Q. And when did you begin working on that report?

A. In April of 2016.

Q. Doctor, when you say you started in April of 2016, what did you start working on in April of 2016?

A. I started reviewing some literature regarding the TVT-O. Just refreshing my memory.

Q. Okay. So is it fair to say -- strike that.

Doctor, prior to April of 2016, had you previously read literature on the TVT-O device?

A. Yes, I had.

Q. Okay. And, Doctor, when did you submit your report in this case, approximately?

A. It was June -- sorry. This is July. Forgive me. June -- I've forgotten the exact date, actually.

Q. Doctor, is it fair to say you submitted your report sometime --

A. Yes, I --

Q. -- in June of 2016?

THE REPORTER: One at a time, please.

Q. June of 2016?

A. Agreed.

Q. Thank you. And, Doctor, at the time you submitted your report in this case, do you know how much time you'd spent preparing that report?

A. Approximately 30 hours.

Q. Doctor, have you submitted an invoice for your time in this case?

A. Yes, I have.

Q. And is that information you brought with you today?

A. It was previously provided in the prior deposition.

MR. KOOPMANN: Mr. Jackson, just for the record, I think it was in the Hoke deposition.

MR. JACKSON: Thank you, Counsel.

Q. Doctor, what is your hourly rate for expert work in this case?

A. $400 an hour.
Q. And is that for any work you do in this case?
A. Yes.
Q. And, Doctor, we have a copy of your CV, so I won't spend an inordinate time on that issue.
Could you tell us when where you went to medial school?
A. I went to medical school at the University of California, San Diego.
Q. Okay. And, Doctor, where did you do your undergrad?
A. At Stanford.
Q. Okay. And you did a residency after medical school?
A. I did.
Q. Where was that?
A. My residency was at the Hospital of the University of Pennsylvania.
Q. And, Doctor, did you do a fellowship?
A. I did not.
Q. Doctor, what professional training do you have post-residency?
A. Just my residency. And ongoing continuing medical education courses.
Q. And, Doctor, when did you complete your

residency?

A. In 1996, July.

Q. And, Doctor, you mentioned continuing medical education. Is that the phrase you used?

A. Yes.

Q. What do you mean by that term?

A. Attending courses sponsored by the various organizations relevant to my specialty; reading materials; maintaining my board certification.

Q. Doctor, what board certification do you hold?

A. The American Board of Obstetrics In Gynecology.

Q. So, Doctor, you are board certified in obstetric -- obstetrics and gynecology; is that correct?

A. That is correct.

Q. Okay. And, Doctor, is that certification done on a state level or is it on the national level?

A. The national level.

Q. And, Doctor, does the American Board of Obstetrics and Gynecology offer a board certification in female pelvic health and reconstructive surgery?

A. They did not at the time that I graduated residency, but they do now.

Q. Okay. They do now.

A. Uh-huh.

Q. And when did they begin offering that board certification?

A. I'm not aware of the exact date. My recollection is sometime around 2006, maybe.

Q. Okay. That's something you have not pursued, though?

A. No, I have not.

Q. Okay. Is it something you could pursue?

A. At this point it would be very difficult for me to pursue that. No, so...

Q. Okay. Doctor, what does a board certification in female pelvic health and reconstructive surgery entail?

MR. KOOPMANN: Object to the form.

THE WITNESS: To be honest, I haven't reviewed the exact requirements. My understanding is that it requires devoting greater than 50 percent of your practice to female pelvic medicine and completing fellowship training. I don't remember if that training requires two or three years post-residency.

BY MR. JACKSON:

Q. Doctor, would it be fair to say that a physician who had a board certification in female pelvic health and reconstructive surgery has training and education above and beyond what you, yourself, have?

A. That would not be fair to say.
Q. And why not?
A. It is a new specialty. And at the time that I completed my training I had the same training and, perhaps, more experience, than many of the current trainees in female pelvic medicine and reconstructive surgery.
Q. Okay. Doctor, you completed your residency 20 years ago?
A. Correct.
Q. Okay. And, Doctor, in that 20 years you could have obtained a board certification in female pelvic health and reconstructive surgery?
MR. KOOPMANN: Object to form.
(Reporter clarification.)
MR. KOOPMANN: Object to form.
THE WITNESS: That is not something that I would have required to practice my specialty. But the specific answer is, I suppose I could have.
BY MR. KOOPMANN:
Q. Doctor, do you know how many -- I'm sorry. Strike that.
Do you know about how many physicians in the United States are board certified in female pelvic health and reconstructive surgery?

A. I do not.

Q. Do you have a sense of if it's more or less than a thousand?

A. My sense is that it's less than a thousand.

Q. Doctor, do you consider yourself an expert in female pelvic medicine and reconstructive surgery?

A. I certainly do.

Q. Doctor, have you performed research in your medical career regarding treatments for stress urinary incontinence?

A. I have not.

Q. Doctor, have you performed any research in your career regarding polypropylene mesh for the treatment of stress urinary incontinence?

A. I have not published research. I have examined my own outcomes.

Q. Doctor, when you say you examined your own outcomes, can you explain what you mean by that?

A. I take care of my patients. I follow them intraoperatively and postoperatively to see how they're doing.

Q. Okay. Doctor, have you authored any publications in your medical career?

A. No, I have not.

Q. Doctor, have you ever served on a peer review

board for a medical journal?

A. No, I have not.

Q. Doctor, have you ever directed a clinical study regarding treatments for stress urinary incontinence?

A. No.

Q. Doctor, have you ever directed any clinical study regarding polypropylene mesh in any application?

A. No.

Q. Doctor, have you ever directed a clinical study of any kind?

A. Not as a principal director, no.

Q. Other than as a principal director, have you ever directed a clinical trial?

A. I'm presently involved in facilitating some clinical trials for a postpartum hemorrhage device.

Q. Doctor, do you currently implant the TVT obturator device?

A. I do.

Q. And, Doctor, when did you last implant a TVT obturator device in a patient?

A. I don't remember the exact date. It's been about six years.

Q. So, Doctor, just so we're clear, when you say you do currently implant the TVT obturator product but

you haven't implanted one in six years, can you just reconcile what that means?

A. That means that I consider the TVT obturator device in armamentarium of devices to be used for stress incontinence. In recent times, I have been preferring to use a mini sling device, but in the appropriate patients I would still use a TVT obturator.

Q. When you say "the appropriate patients," can you tell me what you mean by that?

A. So I counsel my patients as to the risks/benefits of any incontinence procedure. I present the potential morbidity to them and help them come to a decision as to which procedure to perform. Recently my patients have been choosing to have the mini sling.

Q. And, Doctor, when you say morbidity, what does that mean?

A. That means pain after surgery. That means recovery, loss of time from work, potential intraoperative complications, needing to -- well, voiding problems, things I discuss with any surgical patient, uh-huh.

Q. And so, Doctor, is it fair to say that different -- different sling devices for the treatments of stress urinary incontinence have different morbidities associated with them?

A. Different sling devices, that's a broad term. But, yes, because of pubovaginal slings have different morbidities than polypropylene, yes, that's true, uh-huh.

Q. I didn't ask a very good question. Let me ask a better one.

Doctor, does the TVT retropubic device have a different morbidity associated with it than the TVT obturator device?

A. Yes, slightly.

Q. When you say "slightly," what do you mean by that?

A. I think their overall morbidity is about the same, but the particular location of, say, postoperative pain might be slightly different that with the two techniques.

Q. Doctor, when you say their overall morbidities are approximately the same, what's your basis for that statement?

A. That would be the -- review the literature, multi-center randomized trials.

Q. Doctor, have you reviewed some literature as part of your work in this case that points out different complications associated with the TVT retropubic device versus the TVT obturator device?

A. Yes.

Q. When you say the TVT retropubic device and the TVT obturator device have approximately the same morbidities associated with them, what does "approximately" mean in that context?

A. Within a few percentage points either way.

Q. Doctor, are you aware of any published literature where there have been statistically significant differences in complication rates between the TVT retropubic device and the TVT obturator device?

A. Yes.

Q. Do you find those studies relevant and reliable?

MR. KOOPMANN: Object to form.

THE WITNESS: It's hard to comment on some studies. I'd have to know which studies. But in reference to my statement, I would say that there -- when reviewing any study, it's important to note the statistical significance and also the potential clinical significance because to a particular patient a particular morbidity may be more relevant, so...

BY MR. JACKSON:

Q. Doctor, about how many TVT-O procedures have you performed in your career?

A. Approximately 150.

Q. And when did you start using the TVT obturator?

A. So I did not review my exact date of start, but it was approximately 2004.

Q. And, Doctor, I think you said you stopped using it about six years ago?

A. I have not stopped using it, but the last time I used it was approximately six years ago.

Q. I apologize.

Doctor, is it fair to say that you implanted 150 TVT-O devices between 2004 and 2010?

A. Yes.

Q. And, Doctor, how did you come to use the TVT obturator device initially?

A. I was introduced to it, I think, first by reading some articles in the literature. And I went to a training course sponsored by Ethicon to further understand the anatomy of the device and practice on a cadaver.

Q. So, Doctor, you read articles about the TVT obturator device before using it in 2004; is that correct?

A. I do not recall whether they were specific to the TVT obturator device, but they were relevant to the technique, yes.

Q. Doctor, when was the first time you had any interaction with Ethicon?

A. Oh, I really can't remember. I must have had some interaction when I was a resident in the, you know, early '90s.

Q. Okay. Doctor, prior to implanting the TVT obturator in 2004, did you also implant the TVT retropubic device?

A. Yes, I did.

Q. And prior to implanting the TVT retropubic device, are there any other Ethicon devices you implanted before the TVT retropubic?

A. Before the TVT retropubic? Sorry. Ethicon incontinence -- sorry, what was your question? Repeat it again.

Q. Let me ask a better question.

Doctor, did you implant any Ethicon -- strike that.

Doctor, did you use any Ethicon products for any indication, not just stress urinary incontinence, prior to using the TVT retropubic device?

A. Yes.

Q. And what devices would those be?

A. So that is difficult for me to answer because I didn't always pay attention to who the manufacturer

was, but I suspect that I used some of the laparoscopic equipment. And also -- sorry -- I'm sure I used their suture.

Q. And, doctor, when you say "laparoscopic equipment," that's not anything that's permanently implanted, is it?

A. Laparoscopic equipment, they may have made a stapler that that would be permanently implanted. The staples remain.

Q. Okay. Doctor, when -- have you implanted both mechanical cut and laser cut TVT obturator devices?

A. To the best of my knowledge, yes.

Q. Okay. Doctor, when you're doing a TVT obturator surgery, do you know whether it's a mechanically cut or a laser cut product?

A. I do know how to find out, but it's not something that I specifically request one or the other.

Q. Doctor, if you were to hold a mechanically cut TVT obturator mesh in one hand and a laser cut TVT obturator mesh in the hand and just visually looked at them, could you tell a difference?

A. Yes.

Q. And how could you tell a difference?

A. I haven't done this in some time, but I think the edges are slightly different, the look to the edge.

Q. And can you be any more specific there?
A. Not particularly. They look quite similar.
Q. Okay. But you believe the edges might look a little different?
A. Yes.
Q. Okay. And so, Doctor, other than the TVT obturator device, do you currently implant any other Ethicon devices for stress urinary incontinence?
A. Yes, the TVT-Exact.
Q. And when was the last time you implanted a TVT-Exact?
A. Three months ago.
Q. And about how many TVT-Exacts have you implanted in your career?
A. The actual Exact, not that many. Probably 20.
Q. Okay. And, Doctor, other than the obturator and the exact, are there any other Ethicon devices that you currently implant?
A. I have not used any lately, but, yes, the Abbrevo. That's it.
Q. And, Doctor, when did you last implant an Abbrevo?
A. Gosh, more than six years ago. Maybe eight years ago.
Q. And about how many Abbrevos have you

implanted?

A. Four, five.

Q. Okay. Doctor, do you currently implant the retropubic TVT device?

A. Yes.

Q. You do. Okay. And when did you last implant a retropubic TVT device?

A. Forgive me. I may be misspeaking. I equate the TVT-Exact with the retropubic TVT device. Are we speaking of the same thing?

Q. No.

A. Okay.

Q. Doctor, are you aware that there was a retropubic TVT device prior to the launch of the TVT-Exact?

A. Yes, I am.

Q. Okay. And do you currently implant the retropubic non-Exact TVT device?

A. No, I do not.

Q. You do not. Have you ever implanted the retropubic non-Exact TVT device?

A. Yes, I have.

Q. And when did you last implant the retropubic non-Exact TVT device?

A. Gosh, it would have been -- it's really quite

a guess. Probably 2005.

Q. Doctor, when was the first time you ever worked with polypropylene mesh of any type?

A. I really don't remember the exact date. It must have been sometime around 1997 or '8.

Q. And was that for an indication other than SUI repair?

A. Yes.

Q. What would that have been for?

A. Abdominal sacral colpopexy.

Q. Doctor, have you performed Burch procedures for stress urinary incontinence repair?

A. Yes, I have.

Q. And when did you last perform a Burch procedure for stress urinary incontinence repair?

A. Approximately two years ago.

Q. Doctor, would you agree that the Burch procedure is within the standard of care for treating stress urinary incontinence?

A. Yes, it is within the standard of care.

Q. And, Doctor, how many Burch procedures have you performed in your career?

A. Approximately 200.

Q. Doctor, have you attended any Ethicon training?

A. Yes.

Q. Okay. And was that training specific to stress urinary incontinence products?

A. Yes.

Q. Okay. And which products did you specifically attend Ethicon training on?

A. I specifically attended training on the TVT obturator. I attended training on Prolift. And I may have also attended training on the TVT Secure. I can't remember if that was at the same time as the Prolift or not.

Q. And, Doctor, have you ever implanted the TVT Secure?

A. Yes.

Q. You have. And when did you last implant a TVT Secure?

A. It's been many years. Perhaps 2011.

Q. And, Doctor, the TVT obturator Ethicon training you mentioned you attended, do you remember approximately when that was?

A. No. It -- approximately 2004.

Q. And do you remember where you attended that training?

A. I recall it was in Phoenix.

Q. And, Doctor, just can you describe what the

training entailed?

A. It entailed morning of lectures and videos, and then I think the afternoon was a cadaver lab implanting the device.

Q. And, Doctor, did you receive any sort of certificate as a result of that training?

A. I would have. Yes, I did.

Q. Doctor, I'm going to turn to your report, which I think we marked as Exhibit 1.

A. Okay.

Q. And, Doctor, if you'd like to refer to the report you brought with you or Exhibit 1, whichever you prefer.

A. Uh-huh.

Q. Doctor, I'm just going to start on page 5. Could you let me know when you're on page 5 of your report?

A. Yes, I'm on page 5.

Q. And I'm -- this is a section called Clinical Experience & Personal Experience with SUI Treatments; is that correct?

A. That is correct.

Q. And, Doctor, what clinical experience are you describing on this page?

A. That's my care for patients.

Q. And, Doctor, I'm looking at a sentence, the second sentence in the second paragraph. It says, "I learned the procedures after residency, due to the ever-growing body of literature which supported their efficacy in the setting of marked improvement and return to normal function."

Did I read that correctly?

A. Yes, you did.

Q. What do you mean by that sentence?

A. I mean that I chose to learn this technique once I recognized through reading of the literature that it was a technique that would provide great -- a great boon to women in that they can return to work faster and still have an effective procedure for their incontinence.

Q. And, Doctor, you mentioned the literature in this sentence.

A. Yes.

Q. And I'm just curious, can you just explain to me what the ever-growing body of literature means in that context?

A. At that time I typically read The Green Journal and The Gray Journal, and some of the other throw-away publications like Contemporary OB-GYN. And as I saw more and more information regarding the sling

procedures, I recognized that this was something I should learn to do.

Q. Okay. So, Doctor, just so I'm clear, you're -- strike that.

Doctor, are you saying that you -- due to the literature accumulating on the device, you were inspired to go out and start performing the device yourself?

A. That is what I'm saying.

Q. Okay. And, Doctor, further down on page 5, the first sentence of the last paragraph it says, "When the TVT was first introduced, I waited until there was a wealth of peer-reviewed data surrounding it before adopting it into my practice, but I have been overwhelmingly pleased with the results since I have adopted it and other mid-urethral slings."

Did I read that correctly?

A. Yes, you did.

Q. And, Doctor, when you use the TVT in this context, what are you referring to?

A. In this context, I'm referring to the polypropylene mid-urethral sling.

Q. And when you say, "When the TVT was first introduced," are you referring to a specific iteration of the TVT or the entire family of TVT?

A. In this particular sentence I suppose I would

be referring to the first TVT, the retropubic.

Q. Okay. And that would be the non-Exact retropubic?

A. Correct, yes.

Q. And, Doctor, you say you waited until there was a wealth of peer-reviewed data surrounding it before adopting it into your practice, correct?

A. Yes, I did.

Q. And so when did you adopt it into your practice?

A. The -- approximately 2002.

Q. And, Doctor, when did the TVT retropubic -- I'm sorry, strike that.

Doctor, when was the retropubic TVT first marketed in the United States?

A. I think it was in 1998.

Q. Okay. And, so, Doctor, do you believe that prior to 2002 there was inadequate data surrounding the TVT retropubic?

MR. KOOPMANN: Object to form.

THE WITNESS: There was excellent data prior to 2002. I chose to be cautious and wait until it was more widely accepted.

BY MR. JACKSON:

Q. Okay. Doctor, when you say there was

excellent data surrounding the TVT retropubic prior to 2002, is there any specific data you're referring to as excellent?

A. Oh, well, I read the initial -- I think it was an Omsten article.

Could you repeat your question? You were saying prior to 2002?

Q. Let me back up, Doctor. You state here that -- strike that.

Doctor, you waited until 2002 to start using the TVT retropubic device, correct?

A. Correct.

Q. And you state in your report you waited until there was a wealth of peer-reviewed data.

A. I did.

Q. Okay. And so do you believe that prior to 2002, there was a wealth of peer-reviewed data on the TVT retropubic device?

A. I do believe there was a wealth of peer-reviewed data prior to 2002, yes.

Q. So, Doctor, why did you wait until 2002 to start using the TVT retropubic device?

A. Because I had wonderful success with my Burch procedures. I didn't have a strong impetus to change. But as I read the data and realized that women were

doing better, I thought I better look into this a little further.

Q. Okay. So is it fair to say that you wanted to be cautious before you started using it?

A. I typically am cautious, so, yes, it is fair to say that. However, part of my delay in adopting it was I didn't have a need to adopt it due to my good outcomes with the Burch.

Q. Doctor, the next sentence on page 5 states, "I routinely have patients approach me at the grocery store and at social events with tears of gratitude in their eyes for the improvement they have experienced and their quality of life from the mesh sling procedure."

Did I read that correctly?

A. Yes, you did.

Q. And that must be very rewarding.

A. It is.

Q. And about how many times has that happened where a patient approached you in a grocery store?

A. Oh, 50.

Q. And would those 50 patients who approached you in a grocery store include multiple products that you've implanted, not just the TVT obturator?

A. Yes, they would include multiple products.

Q. So, Doctor, the sentence that I just read from

page 5 that begins, "I routinely have patients," does that refer just to the TVT obturator or does it refer to multiple products?

A. It refers to polypropylene sling products generally.

Q. Doctor, can you definitively say that any of those instances involved TVT obturator products?

A. Yes, I can.

Q. And how can you be sure?

A. Well, during that particular time was when my children were playing soccer, and I would see these moms at the soccer field. And at the period of time I was using the TVT-O, I was using it almost exclusively.

Q. And, Doctor, what -- during what time period were you using the TVT-O almost exclusively?

A. About 2004 to about 2009.

Q. And, Doctor, do you recall the last time a woman came up to you in the grocery store and shared a positive experience with a TVT product with you?

A. With any TVT product, not specifically the TVT-O?

Q. Correct.

A. Oh, about a month ago.

Q. And, Doctor, do you recall the last time a woman came up to you in a grocery store and shared a

positive experience with a TVT obturator device?

A. I don't recall an exact date, no, or time.

Q. And, Doctor, are these encounters with patients in the grocery store part of the information you've considered in reaching your opinion that the TVT obturator device is safe and effective?

A. It's part of it. It's not the principal source of my information.

Q. But it's part of it?

A. It's part of it, yes, uh-huh.

Q. And, Doctor, do you intend to discuss at trial any encounters you've had with patients in the grocery store?

A. Only if it's asked of me. It's not the type of information I typically volunteer.

Q. But do you believe those encounters are relevant to your opinion that the TVT-O device is safe and effective?

A. I suppose so, yes, uh-huh.

Q. And would you like to talk about those encounters at trial if you were allowed?

A. Certainly. I don't know, really. As I said, if asked, I will. If I could state one other thing, it's not really relevant to whether I consider the TVT-O is safe and effective. It's more relevant to the fact

that I consider it to have a low morbidity and high patient acceptance.

Q. Okay. Thank you, Doctor.

Can you explain how safety and low morbidity are different concepts? Because I think that's what you said in your last answer.

A. Yeah. Well, safety would apply to life-threatening or significantly life-altering events. And effectiveness would apply to, you know, the -- how well the device worked. In terms of morbidity, there are other less tangible factors, such as how quickly one can walk around a room, whether one can return to work, whether there's, you know, a need to have a catheter placed that might prohibit you from going to the grocery store yourself, you know, things like that.

Q. Okay. So, Doctor, are you offering an opinion in this case that the TVT-O device is safe and effective?

A. Yes, I am.

Q. Okay. And, Doctor, are you offering any opinions in this case regarding the morbidity associated with the TVT obturator device?

A. Yes, I am.

Q. Okay. And, Doctor, how do you believe your opinions about the morbidity of the TVT obturator device

and the safety of the TVT obturator device are different?

A. Well, my opinion is that the TVT device is safe and effective. My opinion is that the TVT-O has low morbidity. So they're not terribly different.

Q. Okay.

A. But it's a bit like comparing apples and oranges. It's hard for me to say they are exactly the same opinion.

Q. Okay. Fair enough.

Doctor, if I could ask you to locate what we marked as Exhibit 3, which is the list of -- the reliance list.

Doctor, just generally, have you reviewed every document on this list?

A. I have looked at every document on this list, yes.

Q. Okay. And, Doctor, about how much time did it take you to look at every document on this list?

A. A long time. Several days.

Q. Several days. When you say "several days," do you mean --

A. I mean --

Q. -- consecutively or working a certain number of hours a day?

A. Working a certain number of hours a day. I would typically set aside one or two hours per day to do so over the span of, perhaps, two weeks.

Q. So what would be your best guess of how many hours you spent reviewing these?

A. My best guess is maybe 30 hours.

Q. 30 hours?

A. Uh-huh.

Q. Okay. And that's just reviewing the materials?

A. Let's say 25 hours just reviewing materials.

Q. Okay. Doctor, do you have an active practice right now?

A. I do, yes.

Q. Where do you currently work?

A. In Templeton, California at the Pacific Central Coast Health Centers.

Q. And you work there as a obstetrician/gynecologist, correct?

A. I do.

Q. And, Doctor, how long have you been in that position?

A. Almost two years.

Q. And, Doctor, you said you reviewed all the materials on this list, correct?

A. Correct.

Q. And is it fair to say you did not discuss all the materials on the list in your report?

A. That is fair to say.

Q. Okay. So how did you go about choosing which materials from this list would be discussed in your report?

A. I wanted to rely on the highest quality of evidence. So principally I chose from the systematic reviews and meta-analyses.

Q. Doctor, would you consider any published peer-reviewed literature that discusses the TVT obturator device as relevant to your opinions in this case?

A. Once again, it would depend on the quality of the evidence.

Q. And, Doctor, you read some Ethicon internal documents that were provided to you, I assume?

A. Yes, I did.

Q. Okay. And how did you determine which ones you were going to list in your report? Strike that.

Doctor, there are a few Ethicon documents listed as footnotes in your report, correct?

A. Yes.

Q. How did you decide which of those to include

in your report from the long list in your reliance materials?

A. If I might take a moment. You're referring to the Ethicon documents that I referenced?

Q. Correct.

A. It was just if it was relevant to my opinion, it was just --

Q. Well, Doctor, I'll represent to you that there are, we'll say, over 100 Ethicon documents on your reliance list. And you --

A. True.

Q. -- only cited a very small fraction of that in your report; is that fair?

A. That's fair.

Q. And how did you select just those very few?

MR. KOOPMANN: Object to the form.

THE WITNESS: I did not rely much on the Ethicon company documents, to be honest, but there were a few specific questions that I had addressed relating to the type of material used. And the only information that I could find relevant to that was in the Ethicon company documents.

BY MR. JACKSON:

Q. Okay. Doctor, how did you become involved in this case in the fall of 2015?

A. I was contacted by Mr. Koopmann.

Q. And at the time you were contacted by Mr. Koopmann in the fall of 2015, did you believe that the TVT-O device was safe and effective?

A. Yes, I did.

Q. And at the time you were first contacted by Mr. Koopmann, did he explain that he wanted you to provide a report stating that the TVT-O device was safe and effective?

MR. KOOPMANN: I object to the form of the question. I think that calls for communications between myself and the witness which is privileged under the rules. So I'm going to instruct the witness not to answer.

BY MR. JACKSON:

Q. Okay. I can ask a better question. Doctor, at the time -- strike that.

Doctor, is it fair to say that no matter -- Doctor, you said in the fall of 2015, when you were first contacted in this case, you held the opinion that the TVT-O device was safe and effective; is that correct?

A. That is correct.

Q. And is it fair to say you didn't see or learn anything that changed your mind?

A. Yes, that's fair to say. If I may elaborate. Reviewing some of the more recent meta-analyses further reinforced that opinion.

Q. So, Doctor, since you began work in this case, have you done any research independently to determine whether your initial view that the TVT-O device was safe and effective was correct?

A. Yes, I looked up -- up to date, I reviewed the recent physician statements by my professional societies.

Q. Doctor, what professional societies are you a member of?

A. American College of OB-GYN, the American Urogynecologic Society.

Q. Doctor, is the American Urogynecologic Society also known as AUGS?

A. Yes. AMA.

Q. Doctor, how did you go about deciding what information to include in your report in this case?

A. I formulated my opinions. And I looked through some of the documents provided to me. And I did a literature search on my own, and looked to see what seemed to reasonably support my -- the opinions that I have stated.

Q. So is it fair to say you had your opinions

first and then you filled in the report with support for those opinions?

MR. KOOPMANN: Object to form.

THE WITNESS: Having been in practice for 20 years and gone to medical school and residency as I have had the opportunity to form some opinions, those opinions would have been subject to change had I found contrary information. But, yes, I did have some opinions before I started the report.

BY MR. JACKSON:

Q. Doctor, you discussed the instructions for use, or IFU, for the TVT obturator in your report, correct?

A. Correct.

Q. How did you determine to discuss the TVT obturator IFU in your report?

A. Well, it has been a subject of question, I think, in prior litigation so I thought it might be relevant.

Q. Okay. And, Doctor, you discuss the background of the TVT retropubic and the TVT obturator in your report --

A. Yes.

Q. -- correct?

And you also discuss literature surrounding

both those devices in your report?

A. Yes.

Q. Doctor, you discuss the IFU for the TVT obturator in your report?

A. Yes.

Q. And, Doctor, you also discuss Ethicon's training programs in your report?

A. Yes.

Q. And you discuss Ethicon's product brochures in your report, correct?

A. Yes, uh-huh.

Q. Okay. And are there any other sections in your report that I didn't just list?

A. Everything is listed here. There may be something that you haven't mentioned.

Q. Okay. Well, how did you decide to include those sections and not other sections?

A. Well, I had a general outline that I felt would be relevant, and then additional material in discussion with counsel to see what might be relevant.

Q. Okay. And how did you come up with that initial general outline?

A. I asked counsel some questions. I asked some of my colleagues what generally goes in a expert report.

Q. Okay.

A. Not relevant to this particular case, but...
Q. Okay. And, Doctor, if I can ask you to turn back to Exhibit 3, the reliance list.
A. Uh-huh.
Q. And I took the liberty of tabbing a page to streamline things. If I could ask you to turn to that tabbed page.
A. Yes.
Q. I had a few questions about some of the things on this page.
A. Okay.
Q. Doctor, do you see just about halfway down the page it says, "FDA 24-Hour Summary"?
A. Yes.
Q. Do you know what document that refers to?
A. I would have to look in the binder. No, I don't remember.
Q. Okay.
A. Can I?
Q. Well, not right now.
A. Okay.
Q. Let me ask, is it your understanding that there's a document labeled in one of the binders called FDA 24-Hour Summary?
A. That would be my understanding.

Q. Okay.
A. Uh-huh.
Q. But sitting here, you're not sure what document this refers to?
A. No, I'm not.
Q. Okay. And, Doctor, a little further down it says, "FDA Executive Summary." Do you know specifically what document that refers to?
A. I do not.
Q. Okay. And, Doctor, the last item on the page says "FDA Stress Urinary Incontinence." Do you know what document that refers to?
A. I'm not certain, but I want to think that's the document stating that the mid-urethral sling is an acceptable treatment for stress urinary incontinence.
Q. So, Doctor, it's your testimony that FDA stress urinary incontinence is an FDA document saying that mid-urethral slings are safe and effective?
A. I had best look at it before I testify that's definitely. May I take the time to find it?
Q. Why don't we do that on a break. Why don't we see if we can locate that document.
A. All right.
Q. I'll admit from my side looking at a document that just says FDA stress urinary incontinence, it's

very difficult to know what that document refers to; is that fair?

A. That's fair.

Q. And, Doctor, the -- about half the documents on this page start with the term "FDA"; is that correct?

A. That is correct.

Q. Okay. And how did you determine which FDA documents to include in this reliance list?

A. Those were provided to me by counsel.

Q. Okay. And, Doctor, what significance, if any, do these FDA documents have in your opinions in this case?

MR. KOOPMANN: Object to the form.

THE WITNESS: Well, the specific document that is most relevant, it was their press release stating that mid-urethral slings are safe and effective.

BY MR. JACKSON:

Q. And why is that the most significant?

A. Because that's my understanding of my expert opinion is that the TVT-O is safe and effective, and the FDA agrees with me.

Q. Doctor, do you believe that -- sorry. Strike that.

Doctor, do you believe that any statements the FDA has made supporting the safety and efficacy of the

TVT obturator device, do you, in fact, support the safety and efficacy of the TVT obturator device?

(Reporter clarification.)

Q. Doctor, do you believe that statements made by the FDA supporting the safety and efficacy of the TVT obturator device do, in fact, support the safety and efficacy of the TVT obturator device?

MR. KOOPMANN: Object to the form.

THE WITNESS: They do support the safety. But the actual safety and effectiveness is -- my opinion is derived from review of the literature more so than an FDA statement.

BY MR. JACKSON:

Q. Okay. Doctor, did you consider any statements made by the FDA in forming your opinion in this case?

A. Well, yes, it's considered. It's on my reliance list, and I believe it supports it, yes.

Q. Doctor, do you believe any statements made by the FDA concerning the safety of the TVT obturator device provide significant support for your opinions in this case?

MR. KOOPMANN: I'll object to the form.

THE WITNESS: It was not my principal source for forming my opinion, so it's hard for me to define significant. I -- it was part of my opinion, but of

minimal significance.

BY MR. JACKSON:

Q. And, Doctor, just generally in regards to the drafting of your report in this case, was it something where you sat down and wrote all 19 pages at once or did you sort of work as you went along?

A. I worked as I went along.

Q. Okay. And, Doctor, were you -- strike that.

Doctor, did you sort of go section by section or just sort of -- how did you go about drafting your report?

A. Yes. I started with the introduction and then I worked section by section. But I might have done a few sections on the same day.

Q. And, Doctor, are there any opinions you intend to offer at trial about the TVT obturator device that are not contained in this report?

A. No. My opinions are in this report.

Q. Doctor, do you intend to offer any opinions at trial about the TVT retropubic device?

A. No.

Q. Okay. Doctor, would you agree with me that you spend several pages in this report discussing the TVT retropubic device?

A. I agree, yes.

Q. Doctor, why do you discuss the TVT retropubic device in your TVT obturator report?

A. Because the TVT retropubic and the TVT obturator, I generally feel, they're modifications of a similar technique.

Q. Doctor, how are the TVT retropubic device and the TVT obturator device different?

A. They employ a different mode of delivery, so they -- the device is implanted in a different direction in the body.

Q. Is it fair to say they have a different surgical technique?

A. Yes, they do have a different surgical technique, yes.

Q. Doctor, do you intend to opine at trial that mid-urethral slings are the gold standard for SUI surgical treatment?

A. I do, yes.

Q. Okay. And what is that based on?

A. The overwhelming body of evidence stating their effectiveness, and their common use by urologists and gynecologists for the treatment of stress urinary incontinence. It is the principally performed procedure.

Q. Okay. And, Doctor, do you intend to opine at

trial that the TVT obturator device is the gold standard for SUI surgical treatment?

A. Only insofar as it is part of the class of mid-urethral slings.

Q. Doctor, is it fair to say you can't point to any specific documents that refer to the TVT obturator as the gold standard for SUI treatment?

A. May I take one moment? I think most of my articles point to mid-urethral slings in general as being the gold standard, but there may be one that states the TVT-O.

Q. If you don't mind, maybe you can look for that over a break --

A. All right.

Q. -- and you can come back to that.

Doctor, why don't we say if you come across an article that specifically refers to the TVT obturator as the gold standard for SUI treatment, you'll make sure to let me know while we're on the record today; is that fair?

A. That's fair.

Q. Okay. Doctor, if I could ask you to turn to page 6 of your report.

Doctor, I'm just looking at the last sentence on this page that says, "The TVT was introduced in the

U.S. in 1998, and soon became the gold standard for SUI surgical treatment."

Did I read that correctly?

A. Yes, you did.

Q. And in this sentence when you say "TVT," are you just referring to the TVT retropubic non-Exact product?

A. Yes.

Q. Doctor, when did the TVT retropubic device become the gold standard for stress urinary incontinence?

A. One cannot assign a specific date to that.

Q. Doctor you say here, "It soon became the gold standard after it was introduced in 1998." Can you give us an idea of what you mean by "soon" here?

A. Oh, 2004.

Q. So, Doctor, it's your testimony that in 2004 the TVT retropubic was the gold standard for SUI treatment?

A. It's my testimony that the mid-urethral polypropylene sling became the gold standard in approximately 2004.

Q. Doctor, what is your definition of gold standard?

A. The procedure to which all others should be

measured.

Q. And, Doctor, do you intend to opine at trial that the design of the TVT obturator device makes it safe and effective?

A. Yes.

Q. Okay. And, Doctor, do you have any experience designing a medical device yourself?

A. Yes.

Q. And what experience is that?

A. Consulting with engineers on development of a product for a postpartum hemorrhage, and offering my opinions through surgeries, feedback to companies in the use of their products in the human body.

Q. Okay. And, Doctor, do you have any experience designing a medical device for SUI treatment?

A. Insofar that I offered feedback, yes. I have not tried to design a device for commercial use. But in my practice performing incontinence surgeries, there have been times where I've had to modify present instruments. So, yes, I've designed things to help me in my surgeries.

Q. Doctor, just so I'm clear, when you say you've designed things to help you in your surgeries, do you just mean you've made modifications to devices for you to use yourself?

A. Yes, uh-huh.

Q. Doctor, have you designed any medical devices for SUI repair that have been commercialized for others to use?

A. Not that I have brought to the commercial production, no.

Q. And, Doctor, have you ever designed a polypropylene mesh device of any kind?

A. Only insofar as I've provided feedback to the reps that have introduced them to me, but, no, I have not originally designed one, no.

Q. Okay. Doctor, the TVT obturator device is inserted through something called the inside-out approach; is that correct?

A. Correct.

Q. And do you intend to opine at trial that the inside-out surgical technique is preferable to other transobturator techniques?

A. I would intend to opine at trial it is preferable in my hands to other techniques, but as a general statement I would not opine that.

MR. JACKSON: Okay. We have been going for a little over an hour. Why don't we take a break.

MR. KOOPMANN: Sure.

THE VIDEOGRAPHER: This marks the end of Disk

1, Volume I, videotaped deposition of Dr. Mareeni Stanislaus. The time on the monitor the 2:23 p.m.

We are now off the record.

(Recess.)

(Exhibit 6-A was marked for identification and attached hereto.)

(Exhibit 6-B was marked for identification and attached hereto.)

(Exhibit 6-C was marked for identification and attached hereto.)

(Exhibit 6-D was marked for identification and attached hereto.)

(Exhibit 6-E was marked for identification and attached hereto.)

(Exhibit 6-F was marked for identification and attached hereto.)

(Exhibit 6-G was marked for identification and attached hereto.)

THE VIDEOGRAPHER: We are back on the record. This marks the beginning of Disk 2, Volume I, in the videotaped deposition of Dr. Mareeni Stanislaus. The time on the monitor is 2:36 p.m. We're back on the record.

MR. JACKSON: While we were off the record we marked as Exhibit 6-A through 6-G binders that

Dr. Stanislaus brought with her.

6-A is titled "SUI Mesh Documents, Binder 1." 6-B is titled "TVT Company Documents." 6-C is titled "TVT-O Company Documents." 6-D is titled "TVT Medical Literature." 6-E is titled "TVT Company/FDA Documents." 6-F is titled "SUI Mesh Documents, Binder 2." And 6-G is titled "TVT literature and Position Statements."

Q. Dr. Stanislaus, have you been able to locate anything indicating what the TVT stress urinary incontinence document in the reliance list may be?

A. I'm sorry. Which one were you referring to?

Q. I'm on the tabbed page, the reliance list.

A. Yes.

Q. The last document is entitled "FDA Stress Urinary Incontinence." Have you yet been able to determine what that document refers to?

A. No.

Q. Okay. Thank you.

Doctor, would you agree with me that it's appropriate for a physician who is going to implant the TVT-O device to have read the instructions for use prior to implanting the device?

A. At some point, yes, the instructions for use.

Q. It doesn't need to be right before they implant it.

A. Yes.

Q. But would you agree they would need to have read it prior to implanting the device?

A. Yes.

Q. And, Doctor, have you personally read the TVT-O instructions for use prior to implanting the device?

A. Yes.

Q. And, Doctor, is it appropriate for a physician to rely on those TVT-O instructions for use to provide a list of known risks associated with the TVT-O device?

A. No, it is not appropriate.

Q. And why not?

A. Because surgeons should rely on their training to know how to perform a procedure, their training being their training in medical school, residency, and in practice. They should also rely on discussions with their colleagues and on literature reports to really determine the way to perform a procedure.

Q. Okay. Doctor, would you agree with me that the TVT-O IFU is one of many pieces of information a physician should consider to determine the risks of the TVT-O device?

A. It is one of many, but it really should not be the place you look for risks of a device.

Q. Okay. Doctor, do you believe the instructions for use for the TVT obturator is an important document?

MR. KOOPMANN: Object to the form.

THE WITNESS: Important is a very subjective thing, but yes. I mean, it's an important document, sure.

BY MR. JACKSON:

Q. Doctor, in your practice as someone who implants the TVT obturator device, do you consider the TVT-O IFU an important tool in learning about risks?

A. No.

Q. Okay. So, Doctor, why did you discuss the TVT-O IFU in your report?

MR. KOOPMANN: Object to the form.

THE WITNESS: Because it was my understanding that Plaintiffs' experts may refer to the IFU. I thought it would be an important thing to discuss.

BY MR. JACKSON:

Q. But, Doctor, you don't independently think it's an important thing to discuss?

MR. KOOPMANN: Object to the form.

THE WITNESS: Sorry. To discuss in what context?

BY MR. JACKSON:

Q. Doctor, do you believe the instructions for

use for the TVT obturator is relevant to assessing the safety of the TVT obturator?

A. No, I don't actually believe that.

Q. Okay. And, Doctor, is it your testimony that you only included a section on the TVT-O instructions for use in your report because you said you think Plaintiffs' experts think it's important?

A. Yes, that is why. And I -- yes, that is why.

Q. Okay.

A. Uh-huh.

Q. Doctor, what opinions do you intend to offer at trial about the TVT-O instructions for use?

A. What I've outlined in my report.

Q. And, generally, what is your opinion with regard to the TVT-O IFU in this case?

A. Well, that it's a document that's explains what the device is and how it's to be used.

Q. Do you hold an opinion in this case that the TVT-O IFU is sufficient with regard to the information that it provides about the TVT-O device?

A. Yes. It's an instructions for use document, and it provides sufficient information on how to use it.

Q. Doctor, do you believe it's a company's response -- strike that.

Doctor, do you believe it's Ethicon's

responsibility to provide -- strike that.

Doctor, do you believe it's Ethicon's responsibility to warn of the risks associated with the TVT-O device?

A. It is -- well, anyone that knows of a risk of a device has an ethical responsibility to report risks; so, in that sense, yes. But I would suggest that they would need to limit it to risks that are specific to the device that they're making.

Q. Okay. Doctor, would you -- would you agree with me that synthetic mesh carries additional risks that are not present in other SUI treatments?

A. Yes, there are different risks.

Q. But the risks that come with polypropylene mesh surgery that are not associated with autologous fascial slings, for example.

A. Yes.

Q. What are some of those risks?

A. Exposure of the polypropylene material. That's the principal one.

Q. Okay. And, Doctor, would you agree that polypropylene mesh because it's a synthetic material can cause a foreign body response?

A. Yes, any synthetic material will cause a foreign body response as it is a foreign body.

Q. Doctor, just a minute ago you mentioned polypropylene -- I'm sorry, Doctor, you mentioned just a minute ago mesh exposure, correct?

A. Yes.

Q. And is your understanding that mesh exposure and mesh erosion are two different concepts?

A. I do use them differently for the most part.

Q. Okay -- I'm sorry.

What's the difference in your understanding?

A. Exposure is visibility of the mesh externally. So exposure through the vaginal mucosa. And erosion I generally consider it to be eroding into an internal organ, so -- such as the bladder or the urethra.

Q. Okay. Doctor, do you believe that the implantation of the TVT device can cause chronic inflammation?

A. It's a, generally, a very rare event but chronic inflammation can occur, yes.

Q. Doctor, do you -- strike that.

Doctor, what's the difference between chronic pain and transient pain following a surgery in your practice?

A. Oh, in my practice? Chronic pain would be pain that lasted beyond three months postoperatively.

Q. Okay. And is transient pain just normal

postoperative pain?

A. Transient pain is a pain of short duration and, yes, that would typically be immediately related in time to the surgery. So postoperatively, yes.

Q. Is it fair to say that transient pain resolves and chronic pain continues for at least longer than three months?

A. Correct. Yes, that would be fair to say.

Q. And, Doctor, would you -- would you agree with me that other physicians in your field would have a very similar definition of chronic versus transient pain?

A. I imagine so. I haven't discussed it specifically, but I imagine so, yes.

Q. Okay. Doctor, is there a significant difference between chronic postoperative pain that may last longer than three months and transient postsurgical pain?

A. Well, I mean by definition they're different in length of time. So, yes, there's a difference and it's significant, sure.

Q. Okay. Doctor, you cite a lot of literature in your report, correct?

A. Yes, I do.

Q. And, just generally, in your report do you cite any literature that tracks chronic long-term pain

following the TVT obturator?

A. I do believe the meta-analysis discuss pain outside the postop period, yes, so I do, uh-huh.

Q. Can you name a study, for example, that you believe tracks chronic long-term pain after the TVT-O device?

A. The Ford study and the Cochrane review.

(Reporter clarification.)

A. The Ford study and the Cochrane review. The Angioli study as well.

Q. Doctor, is there a randomized clinical trial anywhere that has patient safety as a primary endpoint?

A. Yes.

Q. Can you give me an example of the study?

A. The Angioli study.

Q. And patient safety is a primary endpoint in the Angioli study?

A. Yes, it was one of the primary endpoints, uh-huh.

Q. Doctor, are there studies that track dyspareunia, or painful sexual intercourse, as a primary endpoint?

A. I really would have to review my reliance list. I don't remember the specifics of the exact primary endpoints of all these studies. I think

dyspareunia would be lumped into pain. So insofar as it was lumped in, yes, there are studies.

Q. Are you aware of any studies that specifically look at pain with intercourse or you think they'd just all be lumped in with pain generally?

A. I -- let me rephrase it. I do think there is a couple in here that specifically refer to dyspareunia, yes.

Q. And can you name any of those studies here?

A. It would take me a moment to look through. So no. If you give me a moment, I will look through and show you.

Q. Sure.

(Pause while witness peruses documents.)

A. Specific to dyspareunia?

Q. Doctor, I tell you what, is that something we can come back to and you can maybe check on a break? Would that be okay?

A. Yes, that would be okay.

Q. Doctor, would you agree with me that one or more revision surgeries may be necessary to treat adverse reactions after a TVT-O implant?

A. Yes, revision surgery is sometimes necessary.

Q. And sometimes that can be more than one revision surgery?

A. Incredibly rarely. I mean, TVT-O has the lowest risk of requiring revision surgery of any incontinence procedure. But, yes, it can --

Q. And what's --

A. -- be done more than once.

Q. I'm sorry.

And, Doctor, what's your basis for saying that TVT-O has the lowest rate of complications?

A. The Cochrane review suggested a -- that a less than 3 percent risk of exposure --

Q. Okay.

A. -- and a low rate of urinary retention. My clinical experience between the retropubic and the obturator is there's less retention with the obturator. But, yes, there's literature showing that it's got a very, very low complication rate and reoperation rate.

Q. Okay. And, Doctor, are you aware of any literature showing that the TVT-O has higher rates of complications than the 3 percent erosion rate you just mentioned?

A. Oh, yes, there are studies. But, you know, I tried to look at the high-quality studies.

Q. Okay. Doctor, is it your testimony that studies that show a higher than 3 percent rate of complications with the TVT-O are not high-quality

studies?

A. No, not -- no, that is not my testimony. I am sure there are some studies that show a higher than 3 percent rate. But I believe the higher quality studies show approximately 3 percent or less rate.

Q. Doctor, do you believe that the entire TVT obturator can be removed after it's ingrown into a woman's tissues?

A. I -- I believe that would be exceedingly difficult. I suppose it's possible --

Q. Okay.

A. -- but not worth doing so.

Q. Is it fair to say it might require aggressive dissection to get an entire TVT obturator out after its been ingrown?

A. It would be fair to say that there is no reason to ever aggressively dissect and remove an entire TVT-O. But if that was one's desire, yes, it would require extensive dissection.

Q. Doctor, have you personally performed surgery to take TVT device -- I'm sorry. Strike that.

Doctor, have you personally performed revision procedures on TVT obturator devices?

A. Yes, I have.

Q. And about how many revision procedures have

you performed on TVT obturator devices?

A. Specific to the TVT-O, I don't remember exactly. Not very many. Perhaps two or three.

Q. And, Doctor, were those two or three instances something where you were just trimming the mesh or were they a more advanced removal procedure?

A. Again, one would have to define advanced removal. One of them was trimming the mesh. One of them involved some dissection to remove most of the visible -- sorry -- most of the mesh up to a distance of a couple of centimeters either way. So I suppose that's extensive, uh-huh.

Q. And, Doctor, have you ever removed a TVT obturator in its entirety?

A. No, I have not.

Q. Do you know anyone who ever has?

A. No, I do not.

Q. Doctor, the way to manage complications with a TVT-O device is typically to remove a portion of the mesh; is that correct?

MR. KOOPMANN: Object to form.

THE WITNESS: Not necessarily, no. It depends on what the complication is.

BY MR. JACKSON:

Q. Okay. Doctor, if a patient has a mesh erosion

or an exposure of the TVT-O device, is a way to manage that complication to typically remove part of the device?

A. The first treatment you would use would be estrogen cream to promote vaginal healing and epithelialization. But if that is not effective, certainly portions of the mesh can be removed. Typically, though, that can just be done in the office.

Q. Okay. And if a physician is removing a portion of a TVT-O device, the physician has to make a judgment call about how much of the device to remove, correct?

A. Every time a surgeon enters the operating room we make multiple extensive judgment calls with every step we make, with every cut we -- we perform. So, yes, absolutely.

Q. Okay. So you'd certainly agree that the amount of mesh that a surgeon was removing is a judgment call?

A. Well, yes, as well as is the decision to perform incontinence surgery in the first place, yeah, sure.

Q. And if a doctor decides to only remove a small portion of a mesh, you're certainly not here to fault a doctor for choosing how much mesh to remove, correct?

MR. KOOPMANN: Object to form.

THE WITNESS: That's -- it seems a rather hypothetical situation, but I don't think I was asked to fault a physician for any of their specific decisions, no.

BY MR. JACKSON:

Q. Okay. And, Doctor, do you specifically treat patients for chronic pain following TVT obturator surgery?

A. Well, I have not had any patients with chronic pain in -- following TVT obturator surgery in my practice. Would I be willing to treat them? Certainly.

Q. Okay. And, Doctor, you mentioned that on two or three occasions you have performed revision procedures of TVT obturators; is that correct?

A. Yes, that is correct.

Q. And are those revision procedures something you report to the FDA as adverse events?

A. No, I did not report those.

Q. And, Doctor, on the two or three TVT-O revision procedures you've performed, did you perform any tests on the mesh that was removed?

A. I did not, no. Well, other than, you know, looking at it visually. Certainly I had to look at everything. It was -- I imagine that the specimen was

sent to pathology. I didn't send it away for any specific testing, if that's what you mean.

Q. Okay. Are you aware of whether those specimens were sent to pathology or are you just guessing?

A. Specimens are always sent to pathology, so they would have been, yeah, uh-huh.

Q. And would you have reviewed those pathology reports?

A. Yes.

Q. Do you remember anything specific about those pathology reports?

A. They were unremarkable, so, no, I do not.

Q. Doctor, are you aware of underreporting of adverse events in your profession?

MR. KOOPMANN: Object to form.

THE WITNESS: Adverse events occur every day. Not everything is reported.

BY MR. JACKSON:

Q. Doctor, have you ever tested a TVT obturator mesh for degradation?

A. Yes, I've looked at it. I've seen it when I've had to go in on repeat procedures, sure. It seems to be very well intact when I've seen it in human bodies, sure.

Q. And that's just based on your visual inspection without any instruments; is that correct?

A. My visual inspection, my palpation, and, of course, you know, its -- its effectiveness in the body over long-term.

I mean, I have patients now that I have been seeing since 2002, and their meshes are still in place. So presume they are still there working without degradation.

Q. And, Doctor, when you say you've tested a TVT-O device for degradation, your concept for testing there is you visually inspected it and not seen any degradation, and the device is still working in the body so there must not have been any degradation; is that correct?

A. Yes, it would be -- my personal testing of it would be a clinical evaluation of the product over time, yes.

Q. Do you believe there's a clinical significance to degradation?

A. I don't really believe that it's occurring. But if it were occurring, the clinical significance would be the procedure would no longer work.

Q. And so because the procedure's still working there must not have been any degradation; is that

correct?

A. That's correct, yes.

Q. Okay. Doctor, are you familiar with the chemical process of oxidative degradation, whether you agree with it or not?

A. I'm sure, uh-huh, yes.

Q. And, Doctor, have you ever looked at polypropylene mesh under a microscope?

A. No, I have not. I've seen pictures of it described, but, no, I haven't personally.

Q. Doctor, have you ever asked a pathologist about polypropylene degradation?

A. No. I speak with pathologists all the time, but that hasn't really been a question that I would think to ask. Because the times I've removed polypropylene, it looks perfectly intact and undegraded. So, no, I have not specifically asked that question, no.

Q. Doctor, are you aware of published peer-reviewed scientific literature that suggests that polypropylene mesh degrades in the body by oxidative degradation?

A. Yes, I am aware of literature that states that polypropylene degrades.

Q. And you've never -- is it fair to say you've never asked a pathologist whether the polypropylene mesh

does, in fact, degrade inside the body?

A. As I said, I had no reason to ask a pathologist that question. I'm aware of literature that states that it degrades, but I'm also aware of literature that states that it does not degrade. It wasn't really clinically relevant to me to ask a pathologist whether it's degrading.

Q. Okay. Doctor, do you know what type of polypropylene is in the Ethicon SUI products?

A. Polypropylene. I think there's only one type.

Q. Okay. It's the same?

A. Right.

Q. And do you know who manufactures the actual polypropylene? Not the mesh, the actual polypropylene.

A. And, once again, that wasn't particularly clinical relevant to me. I did see somewhere in these documents that it may have been manufactured by Sinoco. But, again, I couldn't tell you with 100 percent certainty that that's where it came from.

Q. And, Doctor, do you know whether there are antioxidants added to Ethicon's propylene?

A. Oh, yes, there are, uh-huh.

Q. And do you know whether pure polypropylene without antioxidants can degrade?

A. Gosh, I haven't ever used pure polypropylene

without the antioxidants so I don't know.

Q. Okay. Doctor, have you ever performed any independent studies to determine whether polypropylene degrades?

A. As I said, I've, you know, looked at the material as I've used it, seen it in the body over time, but I haven't published any papers, no.

MR. JACKSON: If we could mark this Exhibit 8, please.

(Exhibit 8 was marked for identification and attached hereto.)

BY MR. JACKSON:

Q. Doctor, I'm going to represent to you that this is a version of the instructions for use for the TVT obturator. It says "2003" on the bottom of the first page.

A. Yes, it does.

Q. I believe this version was in effect from 2003 to 2004. This one is on your reliance list, I'll tell you that.

Doctor, if I could ask you to turn to the page of this document that says 5 in the middle of the bottom.

A. Okay.

Q. And the number stamped at the bottom

right-hand corner ends in 0834. Are you on that page?

A. Yes, I am.

Q. Okay. Doctor, do you see the section in the middle that says "Contraindications"?

A. Yes, I do.

Q. And it says, "As with any suspension surgery, this procedure should not be performed on pregnant patients. Additionally, because polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential, including women with plans for future pregnancy."

Did I read that correctly?

A. Yes, you did.

Q. Doctor, would you agree with me that this version of the instructions for use doesn't say, for example, that the TVT-O should not be used in obese women?

A. No, it does not say it should not be used.

Q. It doesn't say it should not be used in women who smoke?

A. Why would it say that? But, yes, no, it doesn't say that.

Q. And it doesn't say it should not be used in women with weak connective tissue?

A. Wouldn't that be terrible if we couldn't use

it in any of those women. They'd walk around leaking urine all over the place. But, no, it does not say that.

Q. Doctor, is it fair to assume that Ethicon would have known that a certain -- a certain proportion of the women implanted with the device would be obese?

MR. KOOPMANN: Object to form.

THE WITNESS: Well, insofar as the majority of the U.S. population is trending towards obesity, and that obesity is a risk factor for incontinence, certainly this device should be expected to be used in obese patients.

BY MR. JACKSON:

Q. Fair enough. And Ethicon did not say that those women couldn't get this device, did they?

A. No. No, they didn't.

Q. Okay. And if Ethicon thought that those obese women should not get the device, is that something they would have put in their warning information?

MR. KOOPMANN: Object to form. Foundation.

THE WITNESS: I don't really feel that Ethicon should put such a statement in their IFU. Whether they would have, I -- I really don't know. Well, they didn't, so they -- they didn't.

BY MR. JACKSON:

Q. Sure. And, Doctor, why don't you think such a statement should have been put in the IFU?

A. Well, because for the reasons I stated earlier, that obesity is a huge risk factor for incontinence because incontinence is an incredible public health problem for women.

Surgical procedures need to be developed and exist for these women. The TVT-O device, in particular, happens to be a much safer procedure for an obese woman than other procedures. So I think it might be misleading to put in an IFU that it shouldn't be used in an obese woman.

Q. Doctor, the TVT obturator device is obviously intended for women with stress urinary incontinence, correct?

A. That is correct.

Q. As you said, many women with stress urinary incontinence also have other comorbidities, correct?

A. That is absolutely correct, yes.

Q. And, Doctor, in your opinion, the TVT-O device is a perfectly acceptable device for these women despite their comorbidities, correct?

MR. KOOPMANN: Object to form.

THE WITNESS: In every situation a surgeon has to consider the risks and benefits as they pertain to a

particular patient. So in the correct patient, a TVT-O device is an acceptable device to use, yes.

BY MR. JACKSON:

Q. Doctor, can you give me an example of comorbidity that you may see in a patient where you would choose not to implant the TVT-O device?

A. Prior radiation to the pelvis.

Q. Okay. And why would prior radiation to the pelvis indicate you to not implant the TVT-O device?

A. Because of poor tissue healing.

Q. Okay. And is that kind of common knowledge that any surgeon would know?

A. Yes.

Q. Okay. Doctor, do you see the first bullet point on this same page 5 under Warnings and Precautions where it says, "Do not use Gynecare TVT obturator procedure for patients who are on anticoagulation therapy"?

A. I do.

Q. And is it fair to say a surgeon would not want to implant the TVT-O device on a patient who's on Xarelto, for example?

A. So a surgeon would not want to perform any surgery on a patient that was on anti-coagulation, including Xarelto. So, yes, that's not just limited to

the TVT-O.

Q. But certainly including the TVT-O?

A. Yes.

Q. And that's because the patient could start bleeding during the procedure, right?

A. Absolutely, yes, uh-huh.

Q. Okay. And that is certainly common knowledge among surgeons, correct?

A. Yes, it is.

Q. Okay. Doctor, are you offering yourself as an expert in what should and what should not be included in the TVT obturator devices warnings?

A. I am offering myself as an expert in -- in that, yes.

Q. So you feel like you're an expert in what should and should not be in TVT-O warnings?

A. Insofar as the warnings are directly related to me as a surgeon, yes, I am an expert.

Q. Doctor, if I can ask you to turn to the next page of this document, which says page 6, in the middle. The last four in the bottom right-hand corner are 0835. Do you see the adverse reaction section?

A. Yes.

Q. Okay. The second bullet point says, "Transitory local irritation at the wound site and a

transitory foreign body response may occur. These responses could result in extrusion, erosion, fistula formation and inflammation."

Did I read that correctly?

A. Yes, you did.

MR. KOOPMANN: Object to the form.

BY MR. JACKSON:

Q. And, Doctor, we discussed the definition of transitory to mean what would be typical postoperative pain, correct?

A. Correct.

Q. And transitory pain is certainly different from long-term chronic pain, correct?

A. Yes.

Q. And, Doctor, is there anywhere in this warnings and precautions section or adverse reaction section where it mentions long-term pain?

A. So it does not specifically state long-term pain, but they do mention puncture of nerves. And it also is common knowledge to any surgeon that any surgery can result in a chronic long-term pain. So perhaps not necessary to state that.

Q. Okay. Whether you believe it's necessary or not, would you agree there's no specific mention of long-term or chronic pain?

MR. KOOPMANN: Object to form.

THE WITNESS: Puncture of a nerve by inference suggests long-term chronic pain. But, no, it does not specifically state chronic pain here.

BY MR. JACKSON:

Q. Okay. And, Doctor, is there any mention of acute pain?

A. Well, again, that -- it's common knowledge that all surgeries cause acute pain. As I'm reading this again now, transitory, local irritation equates to pain in my definition. So it does refer to transient pain, yes.

Q. Okay. And is transient pain the same as acute pain in your practice?

A. Oh, yes, certainly.

Q. Okay. Doctor, would you agree with me that there's no mention specifically of pain with intercourse in the adverse reactions or the warnings and precautions section of this document?

A. And, once again, that's just simply a known factor when you're performing surgery in the pelvis that dyspareunia is a potential event. So I don't know why they would specifically put that in there, but I do not see the specific word dyspareunia, no.

Q. Doctor, your testimony is that pain with

intercourse is known to pelvic surgeons who are going to be implanting a mesh device?

A. Yes, that is my testimony.

Q. And so that it doesn't need to be included in here because it's a known risk?

A. Of pelvic surgery, yes.

Q. Okay. Doctor, do you know whether there was ever any language in the TVT IFU prior to 2015 to the effect that there may be more than one revision surgery required after implantation?

A. To my knowledge, prior to 2015, no. But, again, that is, you know, sort of common knowledge that if one has an adverse event from a procedure, that revision surgeries need to be done. I mean, even without using a tape I sometimes have to revise pelvic surgery multiple times.

Q. Doctor, this document mentions that the TVT-O should not be implanted in patients who are on anticoagulation therapy, correct?

A. Correct.

Q. We said that's common knowledge.

A. Yes, that is correct.

Q. It's fair to say there's some common knowledge that was included by Ethicon in this document, correct?

A. Yes, that is correct. But, again, if they

were to put in everything that's common knowledge, this document would have to span years of training. It would probably be 25,000 pages long. I don't think everything I learned about common knowledge happened from a one-page document.

Q. Doctor, the TVT-O device is designed to be implanted without tension, correct?

A. Yes, that is correct.

Q. Okay. And, Doctor, when you're implanting a TVT-O device, how do you determine whether there's any tension on the device?

A. I place a dilator between the urethra and the tape. And then as I'm removing the sheath, I make sure that it doesn't move so that there's a little space beneath the urethra.

Q. Doctor, is it your understanding that Ethicon teaches surgeons how to properly tension the TVT obturator device?

A. Well, yes, they did teach me in the lab, yes.

Q. Doctor, when Ethicon taught you in your TVT obturator training how to tension or test for tension in the TVT obturator device, did they teach you how to account for women who are built differently?

A. I don't recall specifics regarding that. So when I say Ethicon, I mean these are surgeons hired by

Ethicon to teach the procedure. And over time, you know, you consult with surgeons about tensioning. And in terms of implanting it in a specific anatomical type, that is such an individual situation and decision, it would really be not -- I don't really believe it would be Ethicon's place to specifically teach that. It would depend on my own knowledge of anatomy.

Q. Okay. Doctor, do you see the section on this page, page 6, that says "Actions"?

A. Yes.

Q. The last sentence of that paragraph says, "The material is not absorbed nor is it subject to degradation or weakening by the action of tissue enzymes."

Do you see that?

A. I do.

Q. Okay. And do you believe that's a true statement?

A. I do believe that's a true statement, yes.

Q. Doctor, did you read any Ethicon documents specifically dealing with dog studies and Prolene sutures and degradation?

A. Yes, I did.

Q. And if Ethicon had documents that showed that Prolene did, in fact, degrade, would this statement be

untrue?

A. Not necessary -- I mean, no, it depends on what the clinical quality of the study was and how relevant it is to use in this form.

Q. Doctor, did you read any testimony of a Dr. Barbolt, who's an Ethicon employee, in connection with your work in this case?

A. I'm not certain that -- that name is familiar, but I'm not certain.

Q. Do you recall reading anything an Ethicon employee named Dr. Barbolt may have said about degradation?

A. Sorry, I don't recall.

Q. Doctor, to your knowledge have any Ethicon employees testified under oath that the polypropylene mesh in the TVT obturator device does, in fact, degrade?

A. That it does in fact degrade?

Q. Yes.

A. I -- so I, to my knowledge, I don't actually know that. But I'm not quite sure why that would be relevant to my opinion.

Q. Doctor, one of the opinions you hold in this case is that the mesh in the TVT obturator device does not degrade, correct?

A. Correct.

Q. And you just said that you don't believe that it's relevant whether an Ethicon employee stated that it does degrade?

A. Correct. Well, I don't know who that employee is. I don't know what studies he reviewed or what was the basis of his opinion. I mean, I've worked with the material. I've seen it in the patient. I've been practicing 25 -- 24 years as a physician. I've seen Prolene. That's been around that long.

My experience would dictate that it doesn't degrade. So, you know, yes, if that employee specifically worked in that field and had done studies and could show that to me, of course, that would be relevant. But I don't know who this employee is.

Q. Doctor, if I could ask you to take out just your report, which is Exhibit 1. And if I could ask you to turn to Page 15, please.

Doctor, I'm looking at a section entitled, "Plaintiffs' Theories are not Supported by the Published Medical Literature or My Experience."

A. Yes.

Q. Doctor, the second sentence says, "Nor have I seen any evidence of Prolene mesh degradation in my clinical practice. I have not observed degradation of the mesh in the instances in which I have implanted it."

Did I read that correctly?

MR. KOOPMANN: Object to form.

THE WITNESS: Yes.

BY MR. JACKSON:

Q. So, Doctor, is it your testimony that because you have not seen mesh degradation when you're implanting mesh that there must not be degradation?

MR. KOOPMANN: Objection, Counsel. You said implanted," and it says "explanted." And then your follow-up question was based on your misreading of that sentence.

MR. JACKSON: That's my mistake. I apologize. Let me strike that.

Q. Doctor, the second sentence of this paragraph says, "Nor have I seen any evidence of Prolene mesh degradation in my clinical practice. I have not observed degradation of the mesh in the instances in which I have explanted it."

Did I read that correctly?

A. Yes, you did.

Q. Okay. And is it your testimony that because you have not observed degradation of explanted mesh in the two to three instances you've explanted it, that it must not be occurring?

MR. KOOPMANN: Object to form.

THE WITNESS: I have explanted different types of polypropylene mesh on more than two to three occasions. I was referring specifically to two to three occasions of the TVT-O device. I do believe my greater experience is relevant since the material is the same. And, yes, I am testifying that my -- that the fact that I have not observed degradation is the basis of my statement.

There is also, however, data showing that polypropylene does not degrade. And there are published articles that also support my clinical impression.

BY MR. JACKSON:

Q. Doctor, you cite to a number of published studies in your report, correct?

A. I do, yes.

Q. Are any of those studies specifically to laser cut mesh?

A. To be honest, I'm not certain that they're specific to -- oh, yes, yes, there are. There were some studies with devices that were only made with the laser. So I do think there are some in there specific to laser, uh-huh.

Q. Okay. Doctor, would you agree with me that there are -- well, strike that.

Doctor, are there any TVT-O specific studies

that you cite in your report that deal specifically with laser cut mesh?

A. I don't think so.

Q. Doctor, are you offering any opinions that there is a clinical significance -- clinically -- strike that.

Doctor, are you offering an opinion that there is a clinical significance between mechanically cut mesh and laser cut mesh?

A. No, I am not offering opinion that there is a difference clinically.

Q. Doctor, have you seen any Ethicon documents in connection with your work in this case showing that the mechanically cut mesh has a tendency to fray?

A. I think there were some documents with reports from other surgeons suggesting fraying, but I don't have any papers specifically suggesting that it does fray or confirmation that it does fray.

Q. Have you seen documents showing that there is particle loss where doctors are saying they believe this is causing pain?

A. Gosh, I did see documents suggesting particle loss, but, no, not that it was causing pain. Why would it cause pain? But I have not reviewed every document given to Ethicon.

We leave particles of Prolene in patients all the time with Prolene suture and -- I mean, it's just a commonly used material.

Q. Okay. And, Doctor, are you aware that particle loss associated with the mechanical cut mesh was a reason that Ethicon developed the laser cut mesh?

A. My understanding was that they developed a laser cut mesh for ease of production. But I'm sure that they were aware of particle loss. I mean because physicians wrote in about it. But I don't see why they would have used that as a reason. So, no, I was not aware. Sorry.

Q. Okay. And, Doctor, do you know whether Ethicon performed any studies to determine whether there was or was not clinical significance to any particle loss?

A. I would imagine that study would be very difficult to design. But, no, I'm not aware of a specific study.

Q. And, Doctor, you mentioned that you have implanted approximately 150 TVT obturator devices in your career, correct?

A. That is correct.

Q. And do you have a sense of how that breaks down between mechanically cut and laser cut mesh?

A. Forgive me. I do not. They were fairly interchangeable to me. I just used which device was presented to me.

Q. And, Doctor, to your knowledge, does Ethicon still sell both the laser cut and mechanically cut TVT obturator devices?

A. Yes, they do.

Q. Doctor, if I could ask you to turn to page 7 of your report. And at the top of this page it says, "The TVT is a monofilament, large pore, (Type 1), lightweight, Prolene polypropylene mesh sling that is placed without tension under the mid-urethra."

Did I read that correctly?

A. Yes, you did.

Q. And is it fair to say you'd characterize the TVT obturator mesh as macroporous?

A. Yes.

Q. Is macroporous safer than microporous mesh for the T -- for the SUI indication?

A. Yes.

Q. And would you agree with me that smaller pore microporous mesh is less desirable than macroporous mesh for the SUI indication?

MR. KOOPMANN: Object to form.

THE WITNESS: I'm not aware of any currently

available meshes for SUI that are microporous, but they would be less desirable than a macroporous mesh.

BY MR. JACKSON:

Q. Doctor, what support do you have for the statement that the mesh in the TVT obturator is a large pore mesh?

A. There is a Amid classification that states that any mesh, any pore size, greater than 75 microns is macroporous.

Q. And, Doctor, the Amid classification was developed in the hernia application, correct?

A. Yes, it was.

Q. Doctor are you aware of any Ethicon documents where Ethicon employees state that the Amid classification is no longer valid?

A. No, I was not aware of such a document.

Q. Doctor, do you believe you've done enough due diligence to offer the opinion that the TVT-O mesh is macroporous?

A. Yes.

Q. And, Doctor, what have you done to determine that the TVT-O mesh is macroporous?

A. I've looked at it. And at some point I've measured it with a ruler. That's what I would say.

Q. And did you look at the mesh and measure it

with a ruler as part of your work in this case or is that something you would have done prior to becoming involved in this case?

A. It's something I would have done prior to becoming involved in this case.

Q. Okay. And do you remember when you measured the TVT mesh with a ruler how big the pore sizes were?

A. I -- I probably do not remember what it was from that date, but the pore size is 1300 -- 1379 microns.

Q. And that's based on your measurements with a ruler prior to becoming involved in this case?

MR. KOOPMANN: Object to form.

THE WITNESS: That statement is based on the published pore size. My recollection of measuring it with a ruler is it was more than a thousand microns because I was comparing different meshes at the time.

MR. JACKSON: Why don't we take another break.

MR. KOOPMANN: Sure.

THE VIDEOGRAPHER: The time on the monitor is 3:36 p.m. We are now off the record.

(Recess.)

THE VIDEOGRAPHER: We are back on the record. The time on the monitor is 3:47 p.m.

BY MR. JACKSON:

Q. Doctor, what percentage of your current practice involves pelvic floor surgery?

A. Approximately 40 percent.

Q. And what comprises the remaining 60 percent of your practice?

A. Obstetrics and -- well, routine gynecology.

Q. Doctor, on page 1 of your report, Exhibit 1, you note in the education and training section that you have a special interest in pelvic floor surgery; is that correct?

A. That is correct.

Q. What does it mean you have a special interest in pelvic floor surgery?

A. Well, I enjoy taking care of these patients. Women in this community seek me out for pelvic floor procedures. And I keep up on the literature and the data in my field --

Q. Okay.

A. -- so...

Q. And, Doctor, if one of your patients is going to undergo sling surgery for stress urinary incontinence, how do you choose between a retropubic procedure and a transobturator procedure?

A. I choose based on their prior surgical history, their age and activity level, and sometimes

factor into their urodynamic studies.

I counsel patients generally on both techniques, though. And I do allow their assessment of what the potential adverse events are to help me guide which approach I use.

Q. Okay. And how do the patients get information on the relative adverse events of the retropubic versus the transobturator approach?

A. I discuss it with them verbally at one of several consultations. And I encourage them to look at the different patient brochures, and to talk to other women who have had incontinent surgery.

Q. You certainly don't expect patients to keep abreast of the most recent medical literature, do you?

A. No, I do not.

Q. Okay. Does the TVT-O have adverse events associated with it that are not associated with the retropubic TVT device?

A. Yes.

Q. Such as?

A. Such as groin pain.

Q. And does the retropubic TVT have adverse events associated with it that are not typically associated with the obturator device?

A. Yes. Although, with that, it's more that the

retropubic approach has a greater incidence of adverse events than the obturator approach.

Q. Okay. Is it your understanding that the retropubic approach has a higher percentage of bladder perforations associated with it than the transobturator approach?

A. That is correct.

Q. And is it your understanding that the TVT obturator approach has a higher percentage of groin pain associated with it than the retropubic TVT approach?

A. That is my understanding, yes.

Q. And, Doctor, are those examples of different morbidities associated with the TVT obturator and the TVT retropubic?

A. Yes, they are examples, uh-huh.

Q. Okay. So is it fair to say that a higher incidence of groin pain associated with the TVT obturator device is a morbidity that the obturator device has and the retropubic device does not have?

A. Well, that is a true statement. You know, when counseling a patient you have to sort of weigh the relative importance of different morbidities. For example, puncturing a bladder, or a bowel, or a major blood vessel could be a more significant morbidity than, say, a groin pain.

Q. Well, Doctor, for a patient that comes into your office for a prospective SUI repair surgery, how do they know whether groin pain or bladder perforation is a greater concern?

A. Principally from my counseling to them. But any reasonable person with a reasonable level of education would understand that puncturing a -- another organ is probably a more significant complication than groin pain. But, yeah, it would be from my discussion with them.

Q. Okay.

A. Lead them in that direction, uh-huh.

Q. Doctor, when you say that a bladder perforation is a more significant complication than groin pain -- is that what you said; is that correct?

A. I did say that, yes.

Q. Okay. And do you believe that -- let me back up.

Doctor, do you believe in that respect that the TVT obturator is an improvement on the retropubic TVT device?

A. In that respect, yes, it is an improvement, absolutely.

Q. Doctor, how do you stay informed on the relative advantages of the TVT retropubic and TVT

obturator products?

A. So there has been so much published data on both of them that I do feel both of them are safe. But in terms of keeping up to date on what's coming out newly, I read The Green Journal, The Gray Journal, and I do watch for pronouncements by AUGS.

Q. And, Doctor, just briefly, when you say The Green Journal and The Gray Journal, what do those refer to?

A. That's the Journal of the American College of OB-GYN. That's The Green Journal. The Gray Journal is AJOG, which is the American Journal of OB-GYN.

Q. Thank you.

Can we mark this as an exhibit, please. I believe we are on 9.

(Exhibit 9 was marked for identification and attached hereto.)

BY MR. JACKSON:

Q. Doctor, did you discuss an article by Teo, et al., in your report?

A. I don't believe that I did.

Q. Doctor, have you read the article that's been marked as Exhibit 9?

A. When was this from? 2011.

Q. Doctor, are you familiar with this study?

A. I'm trying to remember if I would have read it at the time. I'm not familiar with it at the moment, no.

Q. Okay. And, Doctor, this is from the Journal of Urology. Is that a peer-reviewed article -- I'm sorry -- strike that.

Doctor, is the Journal of Urology a peer-reviewed journal?

A. Yes, it is, uh-huh.

Q. Doctor, do you see on the first page under the Results section where 127 women were randomized to either the TVT retropubic or the TVT obturator device?

A. Yes.

Q. And, Doctor, do you see the second sentence under the Results section that says, "The study was stopped early due to excess leg pain in the tension-free vaginal tape obturator group"?

Do you see that sentence?

A. Sorry. Where was that?

Q. Under "Results" on the first page --

A. Yes.

Q. -- the second sentence. It says the --

A. Oh, yes, I do.

Q. -- "study was" --

A. Yes.

Q. Doctor, the second sentence under Results on the first page says, "The study was stopped early due to excess leg pain in the tension-free vaginal tape obturator group."

Do you see that sentence?

A. I do.

Q. Okay. And, Doctor, further down in that same Results paragraph there's a sentence that says, "More women complained of leg pain after receiving a tension-free vaginal tape-operator (26.4% versus 1.7%, p=0.0001.)"

Did I read that correctly?

A. Yes, you did.

Q. Okay. So, Doctor, is it your understanding that there was a statistically significant difference between leg pain in the obturator group versus the retropubic group in this study?

A. Yes, there is a statistically significant difference. But as a clinician, it's very important to differentiate between statistically significant and clinically relevant, so...

Q. Doctor, is it your understanding that this study was stopped early because of the leg pain in the TVT obturator group?

A. That is what they state, yes.

Q. Okay. Could that be an indication of clinical significance in the TVT obturator group?

MR. KOOPMANN: Object to the form.

THE WITNESS: The authors decided to stop the study because of leg pain. But I would need to read this more carefully to find out why they chose to study it -- to stop it because of leg pain.

Having performed multiple TVT-O procedures, the leg pain I've seen has been transitory and not particularly troubling to the patients. So it would seem unusual that they would need to stop the study based on that.

And it also would appear, you know, just by the technique that you would expect greater leg pain with a procedure that involves an exit point in the leg.

BY MR. JACKSON:

Q. Okay. Thank you.

A. So...

Q. And, Doctor, is it fair to say you were not familiar with this study at the time of -- the time you wrote your report in this case?

MR. KOOPMANN: Object to form.

THE WITNESS: Yes, that would be fair to say.

MR. JACKSON: If we could mark this as Exhibit 10.

(Exhibit 10 was marked for identification and attached hereto.)

BY MR. JACKSON:

Q. Doctor, do you recall seeing this document which we marked as Exhibit 10 before?

A. I do think I've seen it before.

Q. I'll represent to you it is on your reliance list in this case.

A. Uh-huh.

Q. Do you see at the bottom of this case it says Meng Chen is the associate medical director at Ethicon?

A. Yes, I do see that.

Q. Have you ever met her?

A. No, I have not.

Q. Have you reviewed any documents authored by Meng Chen in addition to this one?

A. I do believe there are other documents, yes.

Q. Okay. And do you see that on January 29th, 2009 where Meng Chen is questioning whether or not the general statement about transitory local irritation is still sufficient?

A. Yes.

Q. And do you see what she says above that? About an hour later, she tells Bryan, Lisa, "Pardon me, from what I see each day, these patient experiences are

not 'transitory' at all"?

MR. KOOPMANN: Object to form.

THE WITNESS: Yes, I see that written here.

BY MR. JACKSON:

Q. Okay. And do you see she's talking about the TVT IFU on tape extrusion, exposure and erosion?

MR. KOOPMANN: Object to form.

THE WITNESS: Uh-huh.

BY MR. JACKSON:

Q. Doctor, was that a "yes"?

A. Yes.

Q. Doctor, are you aware that Meng Chen recommended that the IFUs be updated to reflect the kind of calls she was getting about permanent pain, and chronic pain, and inability to have intercourse?

A. Well, aware insofar as it's stated here, yes.

Q. Doctor, do you disagree with the worldwide medical director of Ethicon if she said that these things needed to be changed to update what was happening?

MR. KOOPMANN: Object to form.

THE WITNESS: I'm a surgeon that is not in her position as the associate medical director. She can choose to put whatever information she feels necessary in the IFU. So I -- it really isn't my position to

agree or disagree with her decisions there.

BY MR. JACKSON:

Q. But, Doctor, aren't you holding yourself out as an expert in this case as to what should and should not be included in the TVT warning information?

A. As the person to whom this IFU is directed, yes, I am holding myself up as an expert. So in that situation, yes, I am disagreeing that it would be necessary to put that information in an IFU.

Now, her situation is different. She does not have the experience with the product that I do and use in clinical patients. So she might have come to it from a different standpoint.

Q. Okay. Doctor, do you know that Meng Chen does not have the clinical experience implanting the TVT-O that you do?

A. Well, I have not reviewed her CV. But as the associate medical director for a large company, I can't imagine she's seeing patients daily and performing these surgeries daily.

Q. Would you agree with me that Meng Chen is a medical doctor?

A. Yes, I would.

Q. Okay. And do you have any knowledge one way or another on how many TVT obturator devices Meng Chen

has implanted?

A. No, I do not have direct knowledge, no.

Q. Doctor, do you believe that the IFU for the TVT obturator device should contain information on all known risks?

A. No, I do not agree.

Q. Doctor, if Ethicon is getting reports in post-market surveillance of permanent pain associated with the TVT-O device, does the I -- does the TVT IFU need to be updated to include that information?

A. No, it does not.

Q. Doctor, would you agree -- I just want to make sure we're clear -- that the IFU for the TVT-O is a source of information that a physician may rely on?

MR. KOOPMANN: Object to form. Asked and answered.

THE WITNESS: Yes, it is a source.

BY MR. JACKSON:

Q. Okay. Doctor, if Ethicon were getting reports of dyspareunia in post-market surveillance, do you believe Ethicon had a right to update the IFU to include that information?

A. Ethicon has a right to update and put any information they so choose. But particularly with a report of dyspareunia, I wouldn't feel that it was a

responsibility. As with any self-respecting pelvic surgeon would know that operating in the pelvis carries a risk of dyspareunia. And I would expect that Ethicon would get multiple complaints of dyspareunia since this is a pelvic surgery technique.

Q. Doctor, do you believe that Ethicon should have included the risks of multiple revision surgeries following the TVT-O procedure in the TVT-O IFU?

A. Once again, this is a risk that a surgeon should understand when performing pelvic surgery. So, yes, they have a right to put it in. I don't think they had a responsibility to put it in.

Q. Doctor, is it your testimony that the risk of multiple revision surgeries is a risk that's inherent with any surgery?

A. Yes, it is.

Q. And that's common knowledge that any surgeon would know?

A. Yes, it is. If I may state, particularly for pelvic prolapse and incontinence, when you're actually removing an organ the likelihood of needing to revise it is small.

Q. Doctor, if I could ask you to turn to page 11 of your report.

A. Yes.

Q. Doctor, I'm sorry. Let's, instead, go to -- let's go to Page 15 of your report. I apologize.

A. 15?

Q. Yes, 15.

A. Yes.

Q. And, Doctor, I'm looking at a section called "Plaintiffs' Theories are not Supported by the Published Medical Literature or My Experience." Do you see that section?

A. I do.

Q. And, Doctor, I'm looking at a sentence that's about halfway down that paragraph that starts with, "The excellent safety." Do you see that sentence?

A. Yes.

Q. And it says, "The excellent safety and efficacy reported in the medical literature discussed above, even after 17 years after the procedure, is inconsistent with the idea that mesh is degrading in vivo."

Did I read that correctly?

A. Yes, you did.

Q. And, Doctor, what -- what study are you referring to when you say "17 years"?

A. The Cox study had information about that, yes.

Q. And, Doctor, is it your testimony that the Cox

study is the only 17-year study?

A. No. I should have this at my fingers, but, honestly, it's just common knowledge that the TVTs have published data regarding -- particularly the retropubic data -- out to beyond 17 years, which specific study -- let me try to remember that. It was -- I should have cited it.

Q. Does the Nielson study ring a bell as a study that might have 17-year data?

A. Yes, that -- yes, it does.

Q. And just so we can wrap this up, Doctor, is it your understanding that there's 17-year data for the retropubic non-Exact TVT?

A. Correct.

Q. And, Doctor, for the TVT obturator device that your report is in regards to, what is the longest term study that you're aware of for the TVT obturator device?

A. Eleven years, I think.

Q. And do you know which study that is?

A. I did not cite them appropriately. No, I do not remember.

Q. Okay.

A. But, again, the Cox study refers to both TVT and TVT-O. I can take the time to find it.

Q. Doctor, is it your testimony that the mesh in

the TVT-O device does not curl, rope or fray after implantation?

A. Yes, that is my testimony.

Q. And what is your basis for that opinion?

A. Well, in the few instances that I've seen it in the body, and having made it to explant it, it was not curled, roped or frayed. It continues to be effective. And if it had roped, I would imagine it would not be so. There's also, you know, published tensile strength data on how it behaves under normal circumstances.

Q. Doctor, if I could ask you to turn to page 18 of your report.

A. Certainly.

Q. And, Doctor, in the last paragraph on page 18 there's a sentence that says "In 2015," do you see that sentence?

A. Yes.

Q. It says, "In 2015, Ethicon updated the adverse reaction section of the TVT-O IFU to include some of these risks."

Did I read that correctly?

A. Yes, you did.

Q. And, Doctor, what significance, if any, does Ethicon's 2015 update to the TVT-O IFU have on your

opinions?

A. None. I don't feel that it was significant.

Q. And why don't you feel this IFU update was significant?

A. Because they added additional risks that should be known to pelvic surgeons, and pelvic surgeons should be implanting this device.

Q. Doctor, on page 19 of your report, you include a section on Ethicon's product brochures; is that correct?

A. Yes.

Q. And, generally speaking, do you know whether the TVT-O brochure always disclosed the risk of dyspareunia?

A. I don't believe it did initially. I think it does now, uh-huh.

Q. And, Doctor, have you read the TVT-O brochure prior to implanting the TVT-O device in patients?

A. Yes.

Q. Okay. And, Doctor, have you also -- strike that.

Doctor, have you provided a TVT-O brochure to your patients for them to consider in evaluating whether they'd like to have the TVT-O procedure?

A. Yes, I have.

Q. Doctor, do you believe you're an expert in what sort of warning information should be included in a product brochure such as the TVT-O brochure?

A. Yes, I use product brochures routinely, uh-huh.

Q. Okay. Doctor, you cite a number of meta-analyses in your report; is that correct?

A. That is correct.

Q. And, just generally, what is a meta-analysis?

A. It's a compilation of high-quality evidence, generally randomized controlled trials, put together to form conclusions based on larger numbers than a single trial could provide.

Q. Okay.

A. If I may elaborate. They're not always randomized controlled trials. However, they include not established criteria for what they're going to include, but based on generally established criteria and specifically established criteria by the authors.

Q. Okay. And, Doctor, these meta-analyses, as you said, contain information from multiple clinical trials, correct?

A. That is correct.

Q. And so any given meta-analyses might have information from many different products in it; is that

correct?

A. Yes, that is correct.

Q. Okay. So, for example, I believe you cite a 2014 meta-analyses by an author named Schimpf, S-C-H-I-M-P-F --

A. Yes, I do, uh-huh.

Q. -- correct?

And does that 2014 meta-analyses contain information on many different products beyond just Ethicon products?

A. Yes, it does, uh-huh.

Q. Doctor, do you know what other sling products are included in the studies in that meta-analysis?

A. I have it right here. Yeah, they included Monarc, and Optrics, the Aris and SPARC.

Q. Doctor, those are all different mid-urethral slings from different manufacturers other than Ethicon, correct?

A. Yes, that's correct.

Q. And, Doctor, the Monarc sling you mentioned is made by American Medical Systems; is that correct?

A. Yes.

Q. And I believe the Monarc sling is referred to as a outside-in obturator approach; is that correct?

A. Yes, it is, uh-huh.

Q. And Ethicon's TVT obturator device is referred to as an inside-out obturator device?

A. That is correct, yes.

Q. And so, Doctor, the Monarc and the TVT obturator have slightly different surgical approaches to them; is that fair?

A. Slightly different, yes, uh-huh.

Q. And, Doctor, how can you use data from other products to support the safety of the TVT obturator product?

A. It's essentially the same surgery. You're comparing a -- an approach to a problem. So, you know, an outside-in and an inside-out essentially performs the same function as say, a Burch, but in a completely different way. So a Burch is completely different than a Monarc or a TVT-O. But a Monarc and a TVT-O enter the same spaces. They're similar enough that they should be considered together.

Q. Okay. Doctor, I know the Schimpf meta-analyses and others, they rate the randomized controlled trials that they include; is that correct?

A. Yes, that is correct.

Q. And they might give them a grade of A, B, C, D, for example; is that correct?

A. Yes.

Q. And, Doctor, just generally, do you know how one of these meta-analyses actually grades those randomized controlled trials?

MR. KOOPMANN: Object to form.

THE WITNESS: It would take me some time to specifically lay out exactly how they grade it, but they grade it on data such as patient size, centers used, numbers lost to follow up, data of that nature.

BY MR. JACKSON:

Q. Doctor, is that part of the methodology of how a meta-analyses chooses which data to include?

A. It's part of the study design generally, yes, uh-huh.

Q. And is that something you discuss in your report?

A. For the specific literature I use. I mean, I discuss meta-analysis as being a high-quality data, but I don't discuss the specific methodology used in each --

Q. Okay.

A. -- in each report that I pulled -- report that I pulled or used.

MR. JACKSON: I think that's all the questions I have right now. I may have a few on follow-up after you.

MR. KOOPMANN: Okay.

EXAMINATION

BY MR. KOOPMANN:

Q. Dr. Stanislaus, for the record my name is Barry Koopmann. I'm representing Johnson & Johnson and Ethicon in this case.

Do you practice evidence-based medicine?

A. Yes, I do.

Q. What is evidence-based medicine?

A. It's medicine based on literature analysis and statistical analysis of the literature.

Q. Is some evidence thought of as being more powerful than other evidence?

A. Yes.

MR. JACKSON: Objection. Form.

BY MR. KOOPMANN:

Q. What are the highest levels of evidence?

A. Meta-analysis and systematic reviews.

Q. And what is the lowest level of evidence?

MR. JACKSON: Objection. Form.

MR. KOOPMANN: What's the form objection?

MR. JACKSON: That it's very vague.

BY MR. KOOPMANN:

Q. Okay. Go ahead.

A. Observation, individual case reports.

Q. And where do level 1 studies fall within that

hierarchy of the different level of evidence within the practice of evidence-based medicine?

A. High.

Q. And where do internal company documents, or PowerPoint presentations, or emails, things like that, fall on that hierarchy of evidence?

A. Very low.

Q. Does your TVT-O report that's marked as Exhibit 1 contain your opinions regarding the safety and efficacy of the TVT-O and the labeling for that device?

A. Yes, it does.

Q. And do you hold those opinions to a reasonable degree of medical certainty?

A. Yes, I do.

Q. And are your opinions based, in part, on your education, including your medical school, residency, and continuing education?

A. Definitely, they are, uh-huh.

Q. Are your opinions also based on your clinical training and experience?

A. Yes.

Q. Are your opinions also based on your review of the peer-reviewed literature regarding the treatment of incontinence?

A. Yes.

Q. Are your opinions also based on position statements issued by the relevant organizations that pertain to your specialty?

A. Yes, they are.

Q. Are your opinions also based on the -- any conversations you have with colleagues that are gynecologists or urologists treating incontinence in women?

A. Yes, that does form the basis of my opinions.

Q. Are all of the opinions that you've expressed here today given within a reasonable degree of medical certainty?

A. Yes.

Q. Are the complications that you've seen in your practice consistent with the warnings listed in the adverse reaction section of the IFU for the TVT-O?

A. Consistent with if fewer than, but, yes, consistently.

Q. Is it basic medical and surgical knowledge that postsurgical pain can be chronic or temporary?

A. Yes, it is.

Q. Is it basic surgical knowledge that if pain with intercourse presents itself after any SUI surgery that that pain could be temporary or permanent?

A. Yes, that would be.

Q. Is it also basic surgical knowledge that when an adverse reaction occurs, further surgery may be required to correct that?

A. Yes, that is known.

Q. Even multiple surgeries?

A. Yes, even multiple surgeries.

Q. And that would be true for the Burch procedure or pubovaginal sling procedures?

A. Yes, that would be true for both of those as well. In fact -- yes, I've gone in multiple times on pubovaginal sling procedures more so than I think I have on the obturator.

Q. Do you have many patients who you have implanted with the TVT-O to treat their stress urinary incontinence who experience no complications in connection with that surgery?

A. I'm sorry. Could you repeat that? Have I --

Q. Sure. Do you have many patients who you have implanted with the TVT-O to treat their stress urinary incontinence who have experienced no complications in connection with that surgery?

MR. JACKSON: Objection. Form.

THE WITNESS: Yes, I have.

BY MR. KOOPMANN:

Q. And did you also have some patients who

experienced a complication?

A. Yes, I did.

Q. And when those patients experienced complications, did you treat those complications?

A. I did.

Q. Before you ever used the TVT device or TVT-O device back when you were in medical school, did you learn about basic fundamental risks of any surgery?

A. Yes, I did.

Q. And did you also learn about basic fundamental risks of any surgery during your residency?

A. Yes, of course, I did.

Q. And did you base your opinions regarding the adequacy of the warnings in the TVT-O IFU on all of this experience, education and training that we've discussed?

A. Absolutely, yes.

Q. Can you think of a single randomized controlled trial that says that TVT-O mesh degraded or was cytotoxic?

MR. JACKSON: Objection. Form.

THE WITNESS: No, I cannot.

BY MR. KOOPMANN:

Q. You've performed research in your career for stress urinary incontinence as a part of your continuing reading as a gynecologist and surgeon, correct?

MR. JACKSON: Objection. Form.

THE WITNESS: Yes, of course.

BY MR. KOOPMANN:

Q. Okay. And you testified earlier that you've treated 150 patients, approximately, with a TVT-O; is that right?

A. That is right.

Q. What has your experience been overall with the device in the course of treating those patients?

A. My experience has been that the TVT-O device is an extremely effective procedure for stress urinary incontinence with a very, very low complication rate.

Q. Mr. Jackson asked you a question earlier today about whether you had seen any documents indicating that some Ethicon employee had said the Amid classification is no longer valid. Do you remember that question?

A. I do remember that question.

Q. Just because one Ethicon employee says the Amid classification is no longer valid, does that mean the Amid classification is no longer valid?

A. No, it does not mean that.

Q. If one doctor, or a handful of doctors, reported particle loss outside the context of a scientific study that they thought was associated with pain, what level of evidence would that be?

A. Again, that would be a very low level of evidence. And I think I mentioned that earlier when asked the question.

Q. Did you use Prolene suture before ever using the TVT or TVT-O devices?

A. Yes, I did.

Q. Can you give any estimate of how many times you think you've used Prolene suture in your career?

A. Many thousands.

Q. There were some questions earlier from Plaintiffs' counsel about the wealth of peer-reviewed data on the TVT. Do you remember those questions?

A. Yes.

Q. And that is the wealth of peer-reviewed data that existed before you decided to start using it.

A. That's correct.

Q. Did that data also support your decision to start using the TVT-O device?

A. Yes, of course.

Q. And why is that?

A. Because it's basically a modification of a surgical technique. So knowing that the TVT was effective and safe with extensive data allowed me to consider an improvement in safety by performing the TVT-O.

Q. One of the documents that you have included in Exhibit 5 is a article by a lead author named Cox; is that right?

A. Yes, uh-huh.

Q. Would you turn to that article, please.

A. Okay. Yes.

Q. If you will turn to the last page of that article before the citations start. The last sentence of that article in the conclusion section, what do the authors say?

A. "Based on the literature a new gold standard first-line surgical treatment for women with SUI is the synthetic mid-urethral sling inserted through a retropubic or transobturator approach."

Q. Even if studies do not specifically track dyspareunia or other complications as a primary endpoint, do the studies nonetheless comment on complications such as dyspareunia?

A. Yes, they do.

Q. Would removing all of the sutures used during a Burch procedure potentially require aggressive dissection?

A. Definitely.

Q. Would removing everything that was implanted during autologous fascial sling procedure or pubovaginal

sling procedure using a xenograft or allograft material also potentially require aggressive dissection?

A. Absolutely.

Q. Are there other reasons that a mid-urethral sling procedure using a polypropylene mesh wouldn't work besides sling degradation?

A. Yes, yes.

Q. So just because a sling isn't working doesn't mean the sling has degraded?

A. No. That is absolutely true.

Q. Would you agree that not all brands of meshes are the same?

A. Yes, I would agree with that.

Q. In other words, Prolene is the product used in the TVT family of slings, the mesh in those slings, correct?

A. That is correct.

MR. JACKSON: Objection. Form.

BY MR. KOOPMANN:

Q. And Prolene is not used in other manufacturers' mid-urethral slings, correct?

MR. JACKSON: Objection. Form.

THE WITNESS: Correct.

BY MR. KOOPMANN:

Q. Do you think it was necessary for Ethicon to

warn about not using the TVT-O procedure for patients who are on anticoagulation therapy?

A. No, I do not think it was necessary.

Q. Okay. Why not?

A. Because one should not perform surgery on patients that are anticoagulated. The bleeding risk is too high.

Q. Do you think that a company has an obligation to warn of a risk of using a product if that risk is commonly known by licensed users of that device?

A. No, I don't think it's an obligation if it's commonly known.

Q. One of the studies you have included in Exhibit 5 is a study by Schimpf, and you were asked a few questions about that a little bit ago. Would you, please, pull it out.

A. Yes.

Q. In the first page of the Schimpf study, it says that -- under the Study Design section it indicates that the authors performed "a systematic review including English-language randomized controlled trials from 1990 through April 2013 with a minimum 12 months of follow-up comparing a sling procedure for SUI to another sling or Burch urethropexy"; is that right?

A. Yes.

Q. And that included many studies dealing with the TVT-O device; is that correct?
A. Yes, it did.
Q. And those are listed in Table 1 of the study; is that accurate?
A. That is accurate.
Q. And if you go to Table 3 of that study, one of the complications that is tracked in this study for various incontinence procedures is dyspareunia; is that right?
A. That is right.
Q. What was the rate of the dyspareunia seen with the transobturator mid-urethral slings studied in this particular paper?
A. .16 percent.
Q. What was the rate with pubovaginal slings?
A. .99 percent.
Q. They also track the rate of exposure for various incontinence procedures; is that right?
A. Yes.
Q. What was the rate of exposure in the studies that were analyzed for purposes of the Schimpf study with respect to obturator procedures?
A. 2.2 percent.
Q. And what was the rate of exposure for the

pubovaginal sling procedures?

A. 5.4 percent.

Q. And is this a study that you reviewed and relied upon in forming your opinions regarding the safety and efficacy of the TVT-O?

A. Yes, it is a study I relied upon.

Q. What level of evidence is this considered?

A. Level 1.

Q. Another study that you reviewed and relied upon is the Ford, Cochrane review from 2015; is that correct?

A. That is correct.

Q. That's a rather large study, is that correct --

A. Yes.

Q. -- in terms of the volume of number of pages?

MR. JACKSON: Objection. Form.

THE WITNESS: Yes, it is.

BY MR. KOOPMANN:

Q. Okay. And you have a summary of that Cochrane review in front of you; is that right?

A. That is right.

Q. I want to mark as the next exhibit an excerpt -- excerpt from that study and ask you some questions about those.

(Exhibit 11 was marked for identification and attached hereto.)

BY MR. KOOPMANN:

Q. On the first page of the study where it's below Abstract where it says "Selection Criteria" --

A. Okay.

Q. -- that indicates that the authors looked at "randomized or quasi-randomized controlled trials amongst women with SUI, USI or MUI, in which both trial arms involve a MUS," or mid-urethral sling "operation"; is that right?

A. That is right.

Q. If you'll turn to the next page in the Main Results section. They indicate at the top that they included 81 trials in this study that evaluated 12,113 women; is that correct?

A. That is correct.

Q. Is this high level evidence, this Ford, Cochrane review?

A. Yes, it is.

Q. Is it better evidence than a study involving 100-some patients?

A. Most definitely.

Q. Would it, in fact, include studies like Teo, that we went over earlier, if that Teo study met the

inclusion criteria for this review?

A. Yes, it would.

Q. And in the authors' conclusions section on that same page, it indicates "Mid-urethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence in woman and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long-term. This review illustrates their positive impact on improving the quality of life with women with SUI. With the exception of groin pain, fewer adverse events occur with the employment of a transobturator approach."

Did I read that correctly?

A. Yes, you did.

Q. And does this support your opinions regarding the safety and efficacy of the TVT-O device?

A. Certainly, based on high quality data, yes.

Q. If you'll turn to the next page in this -- in these excerpts. You should you see page 10.

A. Yes.

Q. In the right-hand column it indicates that, "Type 1 meshes are macroporous monofilament meshes"; is that right?

A. That's right.
Q. And what type of mesh is the TVT-O mesh?
A. Type 1.
Q. And it indicates below those bullet points that, "Type 1 mesh has the highest biocompatibility with the least propensity for infection"; is that right?
A. Yes, that's right.
Q. And about six or seven lines below that it says, "Macroporous meshes (pore size in excess of 75 microns) easily allow macrophages, leukocytes, fibroblasts, blood vessels and collagen to transverse the pores; thus macroporous meshes promote tissue host ingrowth with resultant biocompatibility and low risk of infection"; is that right?
A. That is right.
Q. And in the next paragraph it says, "In contrast, microporous meshes (pore size greater than 10 microns) allow bacteria to pass through and replicate, but exclude macrophages"; is that right?
A. That is right.
Q. Then it says, "Multifilament tapes have smaller pore sizes and are thus microporous"; is that right?
A. That is right.
Q. Is the TVT-O mesh monofilament or is it

multifilment?

A. Monofilament.

THE VIDEOGRAPHER: Excuse me, Counsel. I need to change the tape.

MR. KOOPMANN: Okay.

THE VIDEOGRAPHER: This marks the end of Disk 2, Volume I, in the videotaped deposition of Dr. Mareeni Stanislaus. The time on the monitor is 4:43 p.m., and we are now off the record.

(Recess.)

THE VIDEOGRAPHER: We're back on the record. This marks the beginning of Disk 3, Volume I, in the videotaped deposition of Dr. Mareeni Stanislaus. The time on the monitor is 4:48 p.m.

You may continue.

BY MR. KOOPMANN:

Q. Doctor, do you have page 28 of the Ford, Cochrane review excerpts in front of you?

A. Yes, I do.

Q. On page 28 it discusses the types and rate of pain seen with transobturator versus retropubic procedures; is that right?

A. That's correct.

Q. And it indicates in the right-hand column that, "Both groin and suprapubic pain occurrence were

short-lasting, with most resolving within the first six months"; is that right?

A. That is right.

Q. And then if you'll turn to page 30 of Exhibit 11, please. There's a section there discussing "Sexual Function Quality of Life Measures"; is that right?

A. That is right.

Q. And at the bottom of the left-hand column it says, "In all the trials there was significant improvement in sexual function from baseline scores during the follow-up period that spanned 6 to 24 months. There were no significant differences between the groups." Is that right?

A. That is right.

Q. And the two groups being retropubic slings and obturator slings?

A. Yes.

Q. It then says, "A 24-month follow-up, rates of superficial and deep dyspareunia were low, with no difference between the groups."

Did I read that correctly?

A. Yes, you did.

Q. And does that information support your opinions regarding the safety and efficacy of the TVT-O

device?

A. Definitely, yes.

Q. I think one of the documents that you brought along today is the AUGS SUFU updated physician statement.

A. Yes.

Q. And you also have a statement by Douglas Hale, M.D., on June 23rd, 2016 pertaining to that statement?

A. No.

MR. KOOPMANN: Let's mark a copy of that Douglas Hale statement as Exhibit 12, please.

(Exhibit 12 was marked for identification and attached hereto.)

MR. JACKSON: Counsel, do you have one for me?

MR. KOOPMANN: Just one second.

BY MR. KOOPMANN:

Q. Dr. Stanislaus, would you take a moment to review that, please.

(Pause while witness peruses document.)

BY MR. KOOPMANN:

Q. Having read this statement we've marked as Exhibit 13, does this refresh your recollection that you have seen this statement in the last few weeks or --

A. Oh, yes, yes.

Q. Okay. And this is a statement that

accompanied a recent update to the AUGS SUFU position statement?

A. Yes.

Q. And the AUGS SUFU position statement on mesh mid-urethral slings for stress urinary incontinence is something that you -- well, it's something that was first published back in 2014, I think; is that right?

A. That's correct, yes.

Q. And that's a document that you've reviewed, and relied upon, and cited and discussed in your TVT-O general report; is that correct?

A. That is correct.

Q. And was this AUGS SUFU position statement recently updated?

A. Yes.

Q. And that was after you issued your TVT-O general report in this case?

A. Correct, it was.

Q. Is the updated AUGS SUFU position statement also consistent with your opinions regarding the safety and efficacy of the TVT-O device?

A. Absolutely, yes.

Q. And the -- one of the things that Dr. Hale notes in Exhibit 12 is that he was happy to announce that the societies contacted by AUGS undertook their own

thorough review of this document and responded with overwhelming support; is that correct?

A. That is correct.

Q. And he was indicating that he could now say that, in addition to AUGS and SUFU, other organizations supporting our position statement include A-C-O-G, or ACOG, SGS, AAGL, and AUA; is that correct?

A. That is correct.

Q. He went on to say, "Likewise, patient advocacy groups, including NAFC and WHF, also added their support of the document." Is that correct?

A. That is correct.

Q. And the AAGL is the American Association of Gynecological Laparoscopists; is that correct?

A. Yes.

Q. And I think you indicated earlier you're a member of AUGS?

A. I am.

Q. The American Urogynecological Society?

A. Yes.

Q. Another organization that supports this statement is the American College of Obstetricians and Gynecologists?

A. Yes.

Q. Are you a member of that?

A. I am.

Q. Another organization that supports this statement is the National Association for Continence; is that correct?

A. That is correct.

Q. And in the updated AUGS SUFU statement that you have in front of you, that indicates on the third page that the National Association for Continence is the national private nonprofit 501(c)(3) organization dedicated to improving the quality of life of people with incontinence, voiding dysfunction, and related pelvic disorders; is that correct?

A. That is correct.

Q. SGS is the Society of Gynecologic Surgeons; is that right?

A. That is right.

Q. And they're a supporting organization of this statement?

A. Yes.

Q. And, finally, the Womens Health Foundation is a supporting organization of this statement; is that correct?

A. That is correct.

Q. And that is a nonprofit organization dedicated to improving the pelvic health and wellness of women and

girls throughout -- I'm sorry -- through community based programs and services research and events; is that correct?

A. That is correct.

MR. KOOPMANN: Madam Court Reporter, could you please mark this exhibit as Exhibit 14. I'm sorry. Before we that, then, could we mark the AUGS SUFU statement as Exhibit 13?

(Exhibit 13 was marked for identification and attached hereto.)

MR. JACKSON: That's the updated AUGS SUFU statement, correct?

(Reporter clarification.)

MR. KOOPMANN: And counsel just corrected me.

Q. But Exhibit 13 is the updated AUGS SUFU position statement, correct?

A. Correct.

MR. KOOPMANN: Thank you, Counsel.

(Exhibit 14 was marked for identification and attached hereto.)

BY MR. KOOPMANN:

Q. Do you have Exhibit 14 is front of you, Dr. Stanislaus?

A. I do.

Q. And is this an abstract of a couple articles

that has just been published since you issued your TVT-O general report?

A. Yes.

Q. And the abstract on the second page is entitled, "The Myth: In Vivo Degradation of Polypropylene meshes" by Ong, White and Thames. Is that correct?

A. Yes.

Q. And you've had a chance to review this published abstract since issuing your TVT-O general report?

A. Yes, I have.

Q. And what was the conclusion of the authors in that particular abstract?

A. They concluded that Prolene meshes did not undergo meaningful or harmful degradation in vivo.

Q. Does this abstract support your opinion that the -- that clinically significant degradation of the TVT-O does not occur?

A. Yes, it does.

Q. You were asked questions by Plaintiffs' counsel earlier about Exhibit 10, which was an email chain, including a couple emails from Dr. Meng Chen.

A. Yes.

Q. Do you recall those questions?

A. Yes.

Q. Okay. And you were asked about Ms. Chen's -- or Dr. Chen's statement that from what she sees each day these patient experiences are not transitory at all. Do you remember that?

A. I do remember that.

Q. Does the TVT-O IFU say that patient experiences of extrusion and erosion, fistula formation or inflammation are transitory?

A. No.

Q. The Nilson study that was referenced earlier, that had 17-year data on the TVT --

A. Yes.

Q. -- sling, that TVT sling use the same mesh as what's used in the TVT-O; is that your understanding?

A. That is my understanding, yes.

Q. And you cited that TV -- that Nilson study in your report?

A. I did.

Q. Do you have a study by a Dr. Athanasiuo in your Exhibit 5.

A. Yes.

Q. And that study has seven years' data on the TVT-O; is that correct?

A. That is correct.

Q. You were asked some questions earlier about the TVT family of products brochures and whether they contained -- they all contained a warning of a risk of dyspareunia. Do you remember those questions?

A. I do.

Q. Did you counsel your patients about a risk of dyspareunia even before you saw that in a TVT-O brochure?

A. Yes, I did.

Q. How did you know to do that?

A. As a pelvic surgeon, I know to counsel my patients regarding dyspareunia because of my education and training.

Q. You were asked some questions earlier about the Teo study that was marked Exhibit 9. Do you have that in front of you?

A. Yes.

Q. And this was a study that included a total of 127 women who were recruited for this study; is that right?

A. That is right.

Q. If you'll turn to the second page, which is actually numbered 1351 in the Journal.

A. Uh-huh.

Q. Do you see that page?

A. I do.

Q. The bottom of the right-hand column in the Results section, in the second paragraph there, it says, "During recruitment a few studies were published showing similar curates for the 2 procedures but a high incidence of leg pain in patients after receiving a transobturator tape. After discussing these data at an investigator meeting we decided to stop recruitment before the full calculated sample was recruited since it was deemed that clinical equipoise had been lost."

Is that correct?

A. That is correct.

Q. What is higher level evidence, the Teo study or symptomatic reviews in meta-analyses like the Schimpf, Ford, Tommaselli and Ogah systematic reviews that you cited in your TVT-O general report?

A. Of course the systematic reviews and the meta-analyses cited.

Q. And, in fact, do studies like the Schimpf, Ford and Tommaselli and Ogah papers, the systematic reviews and meta-analyses, and Cochrane reviews, take into account studies like Teo in the course of their systematic review and analysis of the literature?

MR. JACKSON: Objection. Asked and answered.

THE WITNESS: Yes, they do. In fact, it says

data on women already recruited would be a value in future systematic reviews in metanalysis in that paper.

BY MR. KOOPMANN:

Q. You also cited some registry studies that discuss very large numbers of patients --

A. Yes.

Q. -- is that correct?

A. That is correct.

Q. And you've cited those and discussed them in your TVT-O general report?

A. I have.

Q. One of those studies is a study by a Dr. Unger and colleagues?

A. Oh, yes, uh-huh.

Q. Do you have that study in front of you in Exhibit 5 or in -- or separately?

A. I have it in Exhibit 5.

Q. Do you have that in front of you now?

A. Yes.

Q. The Unger study was a case controlled study of 3,307 patients receiving a mid-urethral sling over a 10-year period to analyze indications and risk factors necessitating revision surgery; is that right?

A. That's right.

Q. And the revision rate -- strike that.

The revision rate was 2.7 percent for retropubic and transobturator slings over that 10-year period; is that right?

A. That's what they reported, yes.

Q. And the mesh erosion rate was 21.3 percent of those 2.7 percent; is that correct?

A. Yes.

Q. And the vaginal pain or dyspareunia revision rate, in other words, the rate at which women had to have a sling revision due to vaginal pain or dyspareunia, was 7.9 percent of the 2.7 percent, correct?

A. That is correct.

Q. And another study that you reviewed and relied on in forming your opinions was the Jonsson Funk registry study from 2013; is that correct?

A. That is correct.

Q. And that study involved an analysis of a population-based cohort of 188,454 commercially insured women who underwent a sling procedure between 2001 and 2010; is that right?

A. Yes.

Q. In the nine-year cumulative risk of sling revision removal in that patient population of 188,454 women was 3.7 percent; is that right?

A. Absolutely, uh-huh.
Q. You also reviewed and relied on and cited in your TVT-O general report a study by a Dr. Welk --
A. Yes.
Q. -- in 2015; is that correct?
A. Yes.
Q. Would you, please, pull up that study?
A. Okay.
Q. This was a population-based retrospective cohort study of all adult women undergoing synthetic mesh surgery for SUI in Ontario, Canada from April 1st, 2002 through December 31st, 2012, right?
A. That's right.
Q. And that included 59,878 women; is that right?
A. That is right.
Q. And complications were treated in 1,307 of those 59,887 women; is that correct?
A. That's correct.
Q. And that's a 2.2 percent complication rate; is that right?
A. Yes.
Q. And the 10-year cumulative incidence of complications was 3.29 percent; is that correct?
A. Yes.
Q. And that's a study that supports your opinions

regarding the safety and efficacy of the TVT-O device?

A. Yes, definitely.

MR. KOOPMANN: Those are all the questions I have for you. Thank you, Dr. Stanislaus.

MR. JACKSON: I have a few follow up.

Counsel, can I get a copy of Exhibit 13? I didn't get it.

MR. KOOPMANN: Yes. Which is that?

THE WITNESS: That's the updated physician statement.

MR. KOOPMANN: So that -- that copy was just included in her materials. I don't know if I have an identical copy to that, but I have --

MR. JACKSON: Could we just go off the record for a second?

THE VIDEOGRAPHER: The time on the monitor is 5:05 p.m. We're going off the record.

(Off the record discussion.)

THE VIDEOGRAPHER: Going back on the record. The time on the monitor is 5:06 p.m.

FURTHER EXAMINATION

BY MR. JACKSON:

Q. Doctor, could I ask you to take out Exhibit 14, which is marked as Exhibit 14.

A. Yes.
Q. And you were just asked some questions by counsel about a study on the second page of this Exhibit 14; is that correct?
A. That is correct.
Q. And the title of that study is "The myth: In Vivo Degradation of Polypropylene Meshes"; is that correct?
A. Yes.
Q. Are you familiar with any of the authors of this study?
A. No.
Q. Are you aware that Dr. Thames is currently a expert for Ethicon in this litigation?
A. I am, yes.
Q. Okay. And, Doctor, this study that you were just asked about, what level of evidence is this?
A. It's basic science evidence, but low level in terms of the randomized controlled trial level.
Q. So it's not level 1 evidence?
A. No, it is not level 1 evidence.
Q. Doctor, you were asked some questions about an Exhibit 13, which is a AUGS SUFU position statement update that has come out since your expert report in this case; is that correct?

A. That is correct.

Q. And, Doctor, on the first and second pages of this document there's something that says, "Justification for the Position Statement"; is that correct?

A. Yes.

Q. And one of the things that's a justification for this position statement is that the FDA has clearly stated that polypropylene mid-urethral slings is safe and effective for the treatment of SUI; is that correct?

A. Yes, that's correct.

Q. So, Doctor, is the fact that the FDA has spoken on the safety of mid-urethral slings important to your opinions in this case?

MR. KOOPMANN: Object to form.

THE WITNESS: It is important insofar as it forms the basis for this justification, yes.

BY MR. JACKSON:

Q. Okay. Doctor, do you believe you could offer the same opinions in this case without making reference to AUGS or the FDA?

A. Yes.

Q. Doctor, do you believe statements made by AUGS and the FDA are strong evidence that support your opinions in this case?

A. I do.
Q. And would you like to be able to talk about statements made by AUGS and the FDA at trial?
A. Yes, I would.
Q. Doctor, when counsel was asking you some questions a few moments ago, I believe you stated that you've implanted many thousand Prolene sutures in your career; is that correct?
A. That's correct.
Q. Okay. And aside from the Burch procedure, what indications have you implanted Prolene sutures for?
A. Oh, for sacrospinous ligament fixation, multiple vaginal vault suspension procedures, paravaginal defect repairs. Oh, Prolene. Probably used some in repair of abdominal fascia. And, sorry, I did use some on the razin prorare procedures. We used Prolene then.
Q. Okay. Is that it?
A. There may be others, but those are the principal ones, yes.
Q. Doctor, do you know when the Tommaselli study was published?
A. I have to look that up. I think it was 2013. Let me --
Q. Doctor --

A. 2015. Yes, 2015.

MR. KOOPMANN: Counsel, your time's up.

MR. JACKSON: Okay. I have no more questions.

THE WITNESS: Okay.

THE VIDEOGRAPHER: One moment, please.

This marks the end of Disk 3, Volume I, in the videotaped deposition of Dr. Stanislaus. The time on the monitor is 5:12 p.m., and we are now off the record.

THE REPORTER: Did you want a copy of this?

MR. KOOPMANN: We have a standing order with Golkow.

(At the time of 5:12 p.m. the deposition was concluded.)

PENALTY OF PERJURY CERTIFICATE

I, MAREENI STANISLAUS, M.D., hereby declare I am the witness in the within matter, that I have read the foregoing transcript and know the contents thereof; that I declare that the same is true to my knowledge, except as to the matters which are therein stated upon my information or belief, and as to those matters, I believe them to be true.

I declare being aware of the penalties of perjury, that the foregoing answers are true and correct.

Executed on the _____ day of _____,

20___, at _____, _____.

(CITY) (STATE)

_____

MAREENI STANISLAUS, M.D.

- - - - - -

E R R A T A

- - - - - -

PAGE LINE CHANGE

_____ _____ _____

REASON: _____

PAGE LINE CHANGE

_____ _____ _____

REASON: _____

PAGE LINE CHANGE

_____ _____ _____

REASON: _____

PAGE LINE CHANGE

_____ _____ _____

REASON: _____

PAGE LINE CHANGE

_____ _____ _____

REASON: _____

PAGE LINE CHANGE

_____ _____ _____

REASON: _____

PAGE LINE CHANGE

_____ _____ _____

REASON: _____

PAGE LINE CHANGE

_____ _____ _____

REASON: _____

CERTIFICATE OF REPORTER

I, ASHALA TYLOR, CSR No. 2436, in and for the State of California, do hereby certify:

That the foregoing proceedings were taken before me at the time and place herein set forth; that any witnesses in the foregoing proceedings, prior to testifying, were placed under oath; that a verbatim record of the proceedings were made by me using machine shorthand which was thereafter transcribed under my direction; further that the foregoing is an accurate transcription thereof.

That before the completion of the deposition, review of the transcript was not requested.

I further certify that I am neither financially interested in this action nor a relative or employee of any attorney or any of the parties hereto.

In compliance with Section 8016 of the Business and Professions Code, I certify under penalty of perjury that I am a Certified Shorthand Reporter with California License No. 2436 in full force and effect.

WITNESS my hand this 21st day of July, 2016.

_____

Ashala Tylor, CSR #2436, RPR, CRR, CLR